SACRED HEART NURSING COLLEGE

ULTRA TRUST

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Ref. UT: SHNC: 2011

Date: 24.06.2011

To

Dr.Rajaram, M.D. (RT)
Clinical Oncologist
Devaki Scans & Diagnostic Pvt., Ltd.,
26, Theni Main Road, Arasaradi,
Madurai.

Respected Sir / Madam,

Sub: Sacred Heart Nursing College, Madurai – Project work of M.Sc (Nursing) student – permission requested – reg.

.....

We wish to state that **Ms. THANKAM THOMAS** Final year M.Sc. (Nursing) student of Sacred Heart Nursing College has to conduct a Research project, which is to be submitted to The Tamilnadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of University requirements.

The topic of research project is "A quasi experimental study to assess the effectiveness of vegetable oil in reduction of radiation induced xerostomia among patients receiving radiation therapy selected hospital in Madurai".

We therefore request you to kindly permit to do her research work in your hospital under your valuable guidance and suggestions.

Thanking you,

Yours faithfully,

VICE PRINCIPAL.
SACRED HEART NURSING COLLEGE,
ULTRA TRUST, MADURAI-20.

Prof. S. CHANDRAKALA, MSc (N)
VICE PRINCIPAL, HOD OF MED. SUR. DEPT.,
SACRED HEART NURSING COLLEGE
ULTRA TRUST, MADURAI-20

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DEVAKI CANCER INSTITUTE

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26, THENI MAIN ROAD,
ARASARADI,
MADURAI 16.

TO

THE PRINCIPAL
SACRED HEART COLLEGE OF NURSING,
THASILDHAR NAGAR,
ANNA NAGAR,
MADURAI.

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Ms. Thankam Thomas II year M.Sc(N), Sacred Heart College of Nursing, Madurai has been approved to conduct her research project in Radiation Oncology department , Devaki Cancer Institute, Madurai for the period of 3 weeks starting from July 1st onwards

For Devaki Cancer Institute,

Administrative Manager.

DATE : 28.6.2011

26, Theni main Road, Arasaradi, Madurai - 625 016. Phone : 0452-2288831, 2288832
Fax : 0452 - 4200009 e-mail : devakicancerinstitute@ymail.com Website : www.devakicancerinstitute.com

EFFECTIVENESS OF VEGETABLE OIL MOUTH RINSING IN REDUCTION OF RADIATION INDUCED XEROSTOMIA AMONG PATIENTS RECEIVING RADIATION THERAPY.

A DISSERTATION SUBMITTED TO THE TAMILNADU DR.M.G.R MEDICAL UNIVERSITY, CHENNAI, IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF SCIENCE IN NURSING

APRIL 2012

CERTIFICATE

This is the bonafide work of **Ms. Thankam Thomas** M.Sc., Nursing II year student from Sacred Heart Nursing College, Ultra Trust, Madurai, submitted in partial fulfillment of the Degree of Master of Science in Nursing under The Tamil Nadu Dr.M.G.R. Medical University, Chennai.

Dr.Nalini Jeyavanth Santha M.Sc., (N), Ph.D.,
Principal,
Sacred Heart Nursing College
Ultra Trust
Madurai – 625 020.

Place:

Date:

ACKNOWLEDGEMENT

The perfection of work will be of a team work and efforts molded by various persons to complete it successfully. It will not be a fruitful one unless I extend my heartfelt thanks and gratitude to all who have guided me to the treasure of knowledge.

"One and only God Almighty "who pours his blessings each and every minute in our lives deserves all praise. So first of all I thank ***Lord Jesus and Mother Mary*** for their abundant grace, which strengthened me in each and every step through out this endeavour in spite of my weaknesses.

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I wish to convey my thanks to Sri Neelambal Computers for their co-operation during the course of the project.

Last, but not the least I extend my heartfelt thanks to my beloved parents, sister and brother in law for their continuous support, prayers and well wishes.

Finally I thank all my classmates and all those who helped me directly or indirectly during the progress of this study.

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ABSTRACT

Title of the study was to determine the effectiveness of vegetable oil mouth rinsing in reducing radiation induced xerostomia among patients receiving radiation therapy. Quasi experimental pre-test post test control group design was used. Samples were selected using simple random sampling technique. Eligibility criteria were the samples who have been completed seven sittings of radiation therapy for head and neck cancer in Devaki Cancer Institute Madurai. Groningen Radiation Induced Xerostomia Questionnaire was used for assessing xerostomia level. Sixty participants completed pre test post test (on 5^{th} day and 10^{th} day) questionnaires. Experimental group received vegetable oil (10 ml sesame oil) mouth rinsing three times a day before taking meals for continuous 10 days. Mean post test xerostomia level of experimental group (14.2) who had vegetable oil mouth rinsing was lower than the mean post test xerostomia level of control group(43.76). It was found that there was a significant association between the post test level of xerostomia in experimental group and selected variables such as tumor site χ^2 value 4.344 at 1 df(3.84)p (>0.05), previous history of tobacco use and betel nut chewing χ^2 value 8.863 at 3 df (7.82) p (>0.05). These findings suggest that vegetable oil mouth rinsing is effective in reducing radiation induced xerostomia among patients receiving radiation therapy over head and neck cancer.

CHAPTER-I

Introduction

Background of the study

"God didn't promise days without pain, laughter without sorrow, sun without rain, but he did promise strength for the day, comfort for tears, and light for way''- unknown author

Cancerous cells are described as malignant neoplasms. They demonstrate uncontrolled cell growth that follows no physiologic demand. Benign and malignant growths are classified and named by tissue of origin like epithelial connective muscle, neural tissue, haematologic and epithelial tissue .(Suzanne C Smeltzer,Brenda G.Bare, Janice.L.,Minkle and Kerry H.,2008)

Cancers of the head and neck which include cancers of the Oral cavity, larynx (voice box), pharynx, salivary glands and Nose/ nasal passages account for approximately 3 percent of all malignancies in the United States (US National Cancer Institute 2010).India accounts 30% of the world's new cases of cancers of the oral cavity (Ferlay.J., Bray.F., Pisani, P., and Parkin, D.M.,2004) and the highest incidence rate have been observed in Indian subcontinent.

According to Ferlay et al.,(2004) Oral cancer is the most common cancer among men (52,000 new cases per year) third most common among women (31,000 new cases per year)and the second cause of cancer deaths (46,000 deaths in India) .Yeoule BB(2007) in his study on trends in incidence of head and neck cancers in India states that no increase or decrease in age adjusted rates overall for Bangalore and Delhi registries, but a rising trend for Chennai and Bhopal registries over a period of time.

Cancer may be treated in four ways: surgery, chemotherapy radiotherapy and biotherapy.(Gail A Harkness.,Judith R Dincher.,2007).Surgery refers to surgical removal of all malignant tissues before metastasis occurs.(Barbara Long C., Wilma J Phipps.,Virginia L Cassmeyer., 2005).Chemotherapy involves the use of cytotoxic medication which disrupts the cell cycle in various phases by interrupting cell metabolism and replication .(Priscilla Lemone., Karen Burke .,2006).Radiation therapy refers to the use of ionizing radiation to treat tumours which is of two types, external radiation therapy and internal radiation therapy. External radiation is delivered to the patient by machine that generates X rays or gamma rays. The internal radiation therapy involves the placement of specially prepared radio isotopes directly into or near the tumour itself or into the systemic circulation. In recent years cancer treatment research has focused on the use of biologic response modifiers (BRM) which include immunotherapy and biotherapy. BRMs are agents that make the cancer patients biologic response to the tumour cells more effective.(Gail A Harkness et al., 2007).

Radiation therapy is one of the main treatment options for cancer. Ionizing radiation may effectively kill cancer cells, but unfortunately, it may

also unavoidably change the surrounding normal tissues, compromising function and host defence. Fatigue is the most common side effect experienced by cancer patients. Eighty to 93% of patients undergoing RT report symptoms of fatigue. Cancer-related fatigue according to the National Comprehensive Cancer Network (NCCN), is defined as a ‘’distressing persistent subjective sense of physical emotional and or cognitive tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning’. Oral mucositis is a common complication in almost all patients receiving radiation to the head and neck.(Sharon L Lewis.,Margeret McLean Heitkemper., Shannon Ruff Dirksen., Patricia Graber., and Linda Bucher 2007)

Xerostomia is dry mouth resulting from the reduction of salivary production and can result in difficulty eating, swallowing, and trouble speaking.(,JerahThomas., CurtissBeinhorn., DenaNorton., Michael Richardson., Sat- Siri Sumler., and Moshe Frenkel .,2010)

Clinicians may encounter symptoms of xerostomia commonly called ‘’dry mouth’ ’among patients who have been treated with radiation therapy (James Guggenheimer., Paul A Moore (2005). Most oncology patients experience oral dryness, at least temporary during the trajectory of illness and treatment. In fact almost all head and neck cancer patients undergoing radiotherapy experience some degree of xerostomia. The prevalence of xerostomia after treatment of head and neck cancer relates to the extreme radiosensitivity of the salivary glands.(Chambers.,Rosenthal and Weber 2007)

Avraham etal.,(2003) explained that within one week of start of irradiation, after 5 to 10 Gy have been delivered, the salivary output declines by

60% to 90% with later recovery of radiation dosage is moderate . In acute xerostomia (ie occurring concurrent with or immediately after radiation therapy),the patient may experience dry mucosa and thick sticky copious secretions (Bhide,S. A., Miah,A.B., Harrington,K.J., Newbold.K. L., & Nutting, C. M. ., 2009)

Treatment approaches to induce salivation include acupuncture ,electrostimulation ,and cholinergic stimulants such as pilocarpine, and topical stimulation such as sugarless gum and sugarless hard candies .Meticulous oral care during and following treatment includes brushing with fluoride paste ,using a fluoride rinse or gel,flossing when possible, and keeping mouth moist with water or one of the available over the counter saliva substitutes (Thomas E Quinn and Ken Miller.,(2007).

The daily use of topical dry mouth products containing olive oil, betaine and xylitol are safe and effective in relieving symptoms of dry mouth(Ship,McCutcheon,Spivakovsky,Kerr.,2007). In addition to saliva substitutes,other lubricants can be used to provide comfort. Less than 1 teaspoon of butter or vegetable oil placed in the mouth has been reported to lubricate the oral cavity and provide relief of symptoms, although a possible disadvantage to this remedy is personal distaste. (Ryan Iwamoto R., 1996).

Nurse plays an important role in identifying, reporting, and helping patients to deal with side effects of radiation therapy. Educating patients about their treatment regimen supportive care options, and what to expect during the course of treatment is important.(Lewis et al.,2007) In order to improve the quality of life of patients with head and neck irradiation, nurses has an inevitable role to prevent and manage radiation induced xerostomia.

Significance and need for the study

''The devil has put penalty on all things we enjoy in our life. Either we suffer in health or we suffer in soul or we get fat''-Albert Einstein

Many studies have quoted that chronic effects of radiation may be the consequence of acute damage to salivary glands(Li Y, Taylor JM, Ten Haken RK,and Eisbruch A.,2007 Stephens LC, King GK, Peters LJ, Ang KK, Schultheiss TE,and Jardine JH.,1986) chronically affected individuals continue to display significant decreases in unstimulated and stimulated salivary flow for several months or years following radiotherapy .(Dirix P, Nuyts S, Van den and Bogaert W.,2006 Eisbruch A, Kim HM, Terrell JE, Marsh LH, Dawson LA, and Ship JA .,2001 Li et al.,2007)

Salivary glands are exquisitely sensitive to radiation. Early acute effects occur with in a few days or weeks of irradiation, due to high levels of cell death. Late effects occur months or years after irradiation and may be affected by vascular damage and loss of parenchymal cells.Interestingly, there is a third type, termed' consequential late effects' which are hypothesized to result from persistent severe early effects (Hall.,2000).

Xerostomia increases the risk for dental caries, enamel erosion and other dental defects as saliva has antimicrobial properties (Wu.,2008).Saliva also aids with the retention, stability and comfort of dentures .Therefore xerostomia leads to dental instability and increased difficulty in chewing (Arsan, ,Canplot, Delilbasi Dural and, Orhan.,2009). Xerostomia affects the ability to sleep, as rest is frequently interrupted due to oral dryness. The patient may awake frequently with the tongue adhered to the hard palate

and the need to expectorate frequently or manually to remove thick saliva.(Bhide et al.,2009).

Affected individuals display a 50%-60% loss of salivary flow within the first week of radiotherapy (Dirix et al.,2006 Eisburch et al.,2001 Henson BS, Eisbruch A, D'Hondt E, Ship JA.,1999). Loss of acinar cells and glandular shrinkage also occurs during the acute phase (Hoebers FJ, Kartachova M, de Bois J, van den Brekel MW, van Tinteren H, and van Herk M.,2008 Robar JL, Day A, Clancey J, Kelly R, Yewondwossen M, and Hollenhorst H.,2007)

The lack of salivary secretions impacts the ability to eat, sleep, speak, and swallow (Lew and Smith.,2007). A dry mouth can lead to taste changes, which in turn decreases appetite and can lead to subsequent weight loss and malnutrition. (Lew et al.,2007).Patients with xerostomia have difficulty with dry or thick food and their meals are frequently interrupted with sips of fluid aid chewing and swallowing (Bhide et al.,(2009).Glossodynia (burning tongue) also accompanies xerostomia the tongue can become dry depapillated and fissured and may be described as burning and itchy (Camp and Sorell., 2005).The damage to the dorsal epithelium leads to the tongue becoming atrophic or eroded and erythematous. Chelitis fissuring or ulceration in the angles of the mouth, frequently in xerostomia and may be noted on presentation. Camp –Sorell(2005).

Chronic xerostomia is a challenge both to the patient and to the care provider managing their symptoms. Xerostomia is an unfortunately prevalent and distressing side effect of cancer treatment. Poor dentition, a

propensity for oral infections, sleep disturbances, odonophagia and speech disturbance severely impact a patient quality of life.(Anand et al., 2006).

Nurses are the key professionals who have the moral responsibility to improve the quality of life of patients in a cost effective and harmless manner .Oncology nurses in clinical settings encounter xerostomia in head and neck cancer patients. As a nursing management she can advise the patient to lubricate the mouth frequently, The present study will help to find the effectiveness of vegetable oil for lubrication and help to keep the mouth moist for subjects who have received radiation therapy. Since vegetable oil is an edible oil nurses are safe to implement this intervention in clinical setting. In addition to that, it is easily available and cheapest that poor patients can also afford.

TITLE

A quasi experimental study to assess the effectiveness of vegetable oil in reduction of radiation induced xerostomia among patients receiving radiation therapy at a selected hospital in Madurai.

OBJECTIVES

1. To determine the level of xerostomia among patients in experimental group before and after the vegetable oil mouth rinsing.

2. To find out the pre test and post test level of xerostomia among patients in control group.

3. To compare the post test level of xerostomia among the experimental group and control group.

4. To find out the effectiveness of vegetable oil in reducing xerostomia among patients in experimental group.

5.To find out the association between the post test level of xerostomia of experimental group with selected variables.(age, education, locality, tumour classification, site of tumour, radiation field , previous history of betel nut chewing and tobacco use)

HYPOTHESES

All hypotheses were tested at 0.05 level

H1- The mean post test level xerostomia in experimental group who receives vegetable oil mouth rinsing will be significantly lower than their mean pre-test xerostomia level.

.H2-The mean post test xerostomia level among patients in experimental group who received vegetable oil mouth rinsing will be significantly lower than the mean post test xerostomia level among patient with radiation therapy in the control group

H3- There will be a significant association between the post test level of xerostomia among patients with radiation therapy in the experimental group and selected demographic variables (age, education, locality, tumour classification, site of tumour, nature of treatment, radiation field, previous history of smoking, betel nut chewing and tobacco use)

OPERATIONAL DEFINITIONS

Effectiveness

It refers to the change produced by an action or a cause.

In this study it refers to the outcome of vegetable oil in reducing xerostomia among patient with radiation therapy which was assessed through the score

obtained by the subjects through Groningen Radiation induced xerostomia (GRIX) questionnaire.

Vegetable oil

It is oil derived from plants to reduce radiation induced xerostomia. In this study, one sachet containing 10 ml sesame oil was used as mouth rinsing solution for three times a day before meals for continuous ten days. Samples are instructed to avoid rinsing the mouth immediately after the vegetable oil mouth rinsing

Radiation therapy

Radiation therapy is a procedure in which radioactive materials are placed in or near the tumour. In this study patients with external radiation therapy who were exposed for minimum seven sittings for cancer in head, neck area were selected.

Patients receiving radiation therapy

Radiation is the emission and distribution of energy through space or a material medium.

In this study, it refers to patient who were receiving external radiation therapy who had surgery or / and chemotherapy earlier for head and neck cancer admitted in Devaki cancer institute Madurai during data collection period.

Xerostomia

Xerostomia is the dryness of the mouth. In this study it refers to the dryness of mouth for patients who are receiving external radiation therapy, samples who had mild, moderate level of xerostomia in GRIX questionnaire was included.

ASSUMPTIONS

- Nurses have got an important role in providing care to patients who develop radiation induced xerostomia
- Nurses have got responsibility in providing cost effective care to the patients.

DELIMITATION

1. Study was delimited to patients who have developed xerostomia, while receiving radiation therapy over head and neck patients who exposed external radiation therapy for minimum seven sittings

2. Patients who were receiving external radiation therapy in the selected hospital during the period of data collection.

3. The data collection period is limited to 6 weeks.

PROJECTED OUTCOME

This study will help to prove the effectiveness of vegetable oil, which is cost effective and available in the kitchen can be utilized by patients who are receiving radiation therapy for reducing the complication of radiation induced xerostomia.

CONCEPTUAL FRAMEWORK

Conceptualization refers to the process of developing and refining an abstract. A conceptual model gives a clear picture for logical thinking, for systematic observation and interpreting the observed data. The model also gives direction for relevant questions on phenomena and points out solutions to practical problems. To describe the relationship of concepts in the study, open system model by J.W Kenny's is used.

Open system model serves as a model for reviewing, people as interacting with the environment. Open system model is a set of related definitions, assumptions and prepositions which deal with reality

as an integrated hierarchy. ‘systems model focuses in each system as a whole, but pays particular attention to the interaction of its part or subsystems. A system is a group of elements that interact with one another in order to achieve a goal. The following are the major concepts of the theory

THE INPUT

The input is the matter, energy and transformation that enter the system .In this study input is the manipulation or intervention which was done for experimental group i.e. making the subjects to rinse the mouth with vegetable oil (sesame oil 10ml), and instruct to repeat the procedure three times a day, avoid rinsing the mouth with water immediately after vegetable oil mouth rinsing and keep the sesame oil in the mouth for 30 sec.

THROUGH PUT

Through put is the use of biologic, physiologic and sociocultural subsystem to transform the input. In this study it refers to lubricating and moisturizing effect of vegetable oil.

OUTPUT

Output is the return of matter, energy and information to the environment in the form of both physical and psychosocial behaviour

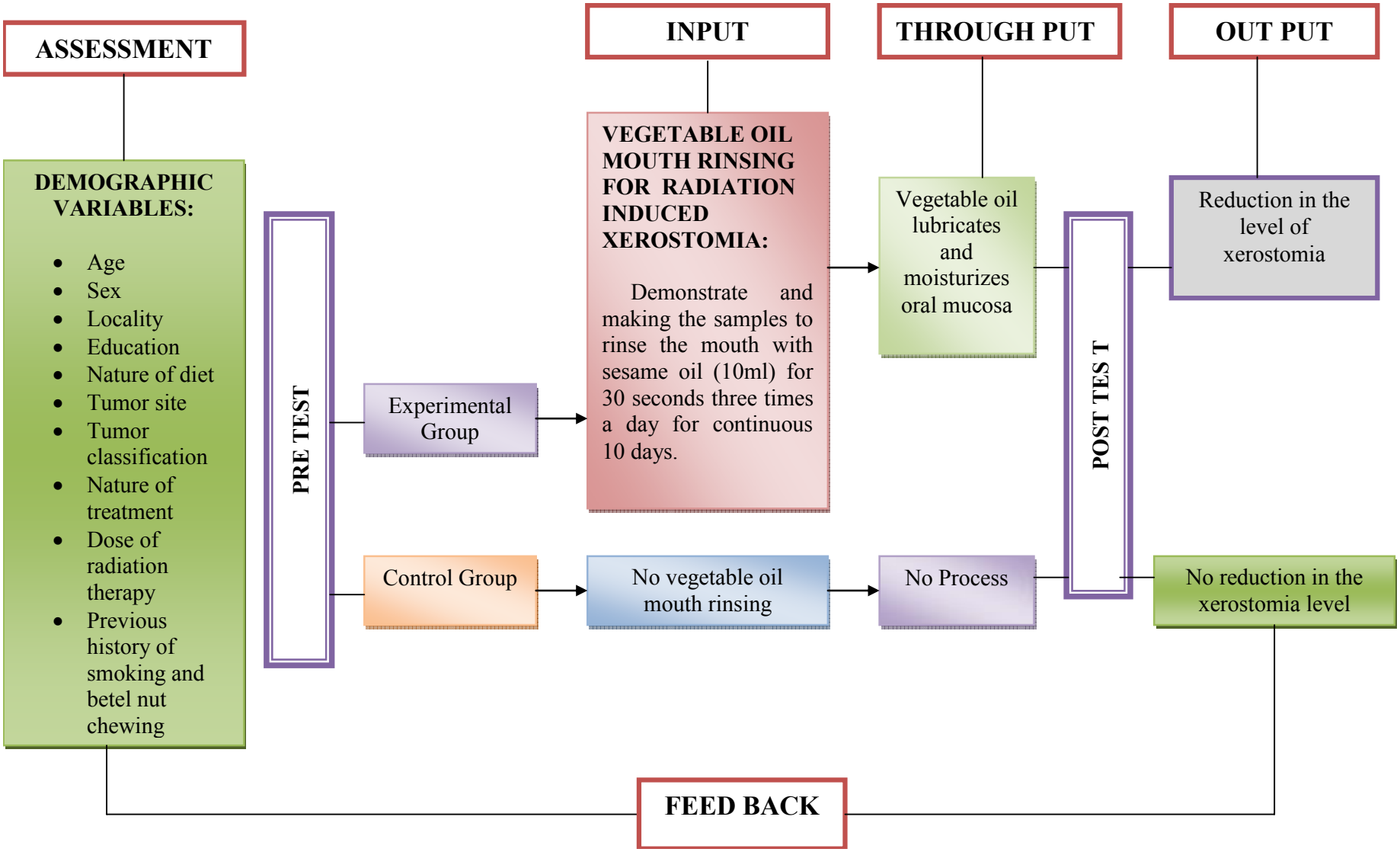
. In this study it refers to the reduction in the level of xerostomia as measured by post test using Groningen Radiation Induced Xerostomia Questionnaire.

FEEDBACK

Refers to the environment response to the system out used by the system in adjustment correction and accommodation to the interaction with the environment.

In this study, it is used, if there is no reduction in the level of xerostomia. Feedback should be given and the sample should undergo assessment process.

Figure:1 **CONCEPTUAL FRAMEWORK BASED ON JW KENNY'S OPEN SYSTEM MODEL**



CHAPTER II

Review of literature

Review of literature in this chapter is discussed under the following heading

1. Prevalence and incidence of head and neck cancer
2. Problem experienced by the patient receiving cancer treatment.
3 Effectiveness of vegetable oil in reducing the xerostomia
4. Literature related to role of nurse in reducing xerostomia

1. Prevalence and incidence of head and neck cancer

Balaram P., et al(2002) conducted a case control study on the influence of smoking, drinking, paan-chewing and oral hygiene in producing oral cancer in 3 areas of southern India (Bangalore, Chennai and Trivandrum) The sample were 591 incident cases of cancer of the oral cavity (282 women) and 582 hospital controls (290 women), frequency-matched with cases by age and gender. Odds ratios (ORs) and 95% confidence intervals (CIs) were obtained from unconditional multiple logistic regressions and adjusted for age, gender, , education, chewing habit and (men only) smoking and drinking habits. Low educational attainment, occupation as a farmer or manual worker and various indicators of poor oral hygiene were associated with significantly increased risk. An OR of 2.5 (95% CI 1.4-4.4) was found in men who smoked 20 or more bidi . The OR for alcohol drinking was 2.2 (95% CI 1.4-3.3). The OR for paan chewing was more elevated among women (OR 42; 95% CI 24-76) than among men (OR 5.1; 95% CI 3.4-7.8). A similar OR was found among chewers of paan with (OR 6.1 in men and 46 in women) and without tobacco

(OR 4.2 in men and 16.4 in women). Among men, 35% of oral cancer is attributable to the combination of smoking and alcohol drinking and 49% to pan-tobacco chewing. Among women, chewing and poor oral hygiene were risk factors of 95% of oral cancer.

Iype EM, Pandey M, Mathew A, Thomas G, Sebastian P, and Nair MK.,(2001) conducted a retrospective study on Oral cancer among patients under the age of 35 years between 1982-1996. Samples were selected using the tumour registry data of Regional Cancer Centre (RCC), Trivandrum, Kerala, India. Detailed clinical, treatment and follow-up data were obtained from the computerised records of RCC and recorded on a preset proforma. This was analysed with emphasis on age, sex, risk factors, site, histology, clinical extent and treatment methods and survival in the study group. The survival analysis was done using the Kaplan-Meier method and the difference in survival was analysed using log-rank test. Results showed that out of 264 patients analysed, tongue was the commonest site identified in 136 (52%) patients followed by buccal mucosa in 69 (26%) patients. A male female ratio of 2.3:1 was observed with a significantly higher male preponderance in buccal mucosa (4.3:1). Prior exposure to tobacco or alcohol was noted in 59.4% patients, with more habitués in buccal mucosa cancer. Histological confirmation was present only in 83.7% patients and among them most were squamous cell carcinoma (85.9%). Radiotherapy, surgery or combined modalities of treatment were employed for majority of patients. The 5-year survival was 57.3%. The stage of the tumour was found to be significant in predicting disease free survival (P=0.03). Conclusion of the study was the importance of early detection for clinical down staging is stressed. There is a need to investigate the aetiology of intra oral

cancers in younger patients since a significant proportion (almost 40%) of these patients do not have associated risk factors for cancer.

Rao DN and Desai PB.,(1998) conducted a case control study on risk assessment of tobacco, alcohol and diet in cancers of base tongue and oral tongue at Tata Memorial Hospital, Bombay, during the years 1980-84.There were 142 male AT (anterior portion of the tongue) patients and 495 BT(base of the tongue) . 635 interviewed male patients who were free of any disease were considered as control. Bidi smoking was found to be a significant risk factor for BT patients and tobacco chewing for AT patients respectively. Alcohol drinkers showed about 45% to 79% excess risk for both sites of tongue cancer. Illiteracy and non vegetarian diet proved to be a significant factor for AT patients only. The study explained that the location of cancer is related to the type of tobacco use and other related habits .

Van der MM., Leyten EM, Gavarasana S, Vandenbroucke JP, Kahn PM, and Cleton FJ.,(1993) conducted a cross sectional study on reverse smoking as a risk factor for palatal cancer in rural Andhra Pradesh, India .A total of 480 randomly selected persons were interviewed. Information about smoking status, diet and access to mass media was obtained in each case and an examination of the oral cavity was performed. Reverse smoking of chutta was practised by 33% of the total rural population. The prevalence rate of all palatal lesions was 55%.The prevalence rates of the separate lesions: leukoplakia palatal, palatal keratosis and palatal cancer, were 9.8%, 18.1% and 1.9%, respectively. The presence of pre-malignant lesions was strongly associated with reverse smoking and also associated with conventional chutta smoking. Reverse smoking induced significantly more lesions than conventional

chutta smoking, and was a major determinant of subsequent palatal cancer: all 9 newly diagnosed palatal cancers were observed within the group of reverse smokers. There was an inverse relationship between the incidence of palatal lesions and vitamin A intake.

Louise Davies and H. Gilbert Welch.,(2006) conducted a study on epidemiology of head and neck cancer in the United States. Total of 75,000 cases of head and neck cancer were diagnosed in 2001. Incidence is rising in thyroid (up 52%), bone (43%) soft tissues (20%), salivary (20%), tongue (16%), tonsil (12%), and nose (12%). Incidence is falling in lip (down 58%), hypopharynx (35%), cervical esophagus (32%), oropharyngeal mucosa (26%), and larynx (26%). There were 30,000 deaths from head and neck cancer in 2001.They recommended further investigation of risk factors,diagnostic practices, and management strategies can be studied in detail.

Anil k.Chaturvedi.,Eric A. Engels.,William .e. Anderson.,and Maura L Gillison(2008) conducted a study on Incidence Trends for Human Papillomavirus (HPV)–Related and –Unrelated Oral Squamous Cell Carcinomas (OSCCS) in the United States. Data from nine Surveillance, Epidemiology, and End Results program registries (1973 to 2004) were used to classify Oral Squamous Cell Carcinoma by anatomic site as potentially HPV-related (n = 17,625) or HPV-unrelated (n = 28,144). Join point regression and age-period-cohort models were used to assess incidence trends. Life-table analyses were used to compare 2-year overall survival for HPV-related and HPV-unrelated OSCCs .HPV-related OSCCs were diagnosed at younger ages than HPV-unrelated OSCCs (mean ages at diagnosis, 61.0 and 63.8 years, respectively; $P <$ .001). Incidence increased significantly for HPV-related

OSCC from 1973 to 2004 (annual percentage change [APC] = 0.80; $P < .001$), particularly among white men and at younger ages. By contrast, incidence for HPV-unrelated OSCC was stable through 1982 (APC = 0.82; $P = .186$) and declined significantly during 1983 to 2004 (APC = −1.85; $P < .001$). When treated with radiation, improvements in 2-year survival across calendar periods were more pronounced for HPV-related OSCCs (absolute increase in survival from 1973 through 1982 to 1993 through 2004 for localized, regional, and distant stages = 9.9%, 23.1%, and 18.6%, respectively) than HPV-unrelated OSCCs (5.6%, 3.1%, and 9.9%, respectively). During 1993 to 2004, for all stages treated with radiation, patients with HPV-related OSCCs had significantly higher survival rates than those with HPV-unrelated OSCCs. The proportion of OSCCs that are potentially HPV-related increased in the United States from 1973 to 2004, perhaps as a result of changing sexual behaviors.

Saima Chaudhry et al.(2008) conducted a study on estimating the burden of Head and Neck Cancers in the Public health sector of Pakistan. Data were obtained from the central body governing of all the cancer centres in the country. The frequency of treated HNCAs out of the total body cancers treated across Pakistan was found to be 14.5%. Highest prevalence rates amongst all cancers were noted in Sind, notably in Karachi and Jamshoro, followed by Multan in Punjab and as much lower frequency in Peshawar in the North West Frontier Province. This variation presumably reflects levels of betel quid consumption but more data are needed to be gathered in a comprehensive way if the findings are to be applicable for improvement of the national cancer control program.

Problem experienced by the patient receiving cancer treatment

Fossa SD, Dahl AA and Loge JH.(2003) conducted a study at Oslo in Norway to investigate the prevalence of chronic fatigue (CF), the levels of anxiety and depression, and the correlation between these conditions in long-term survivors of testicular cancer (TCSs). Occurrence of CF in TCSs is compared with findings in male survivors of Hodgkin's disease (HDSs) and in males from the general population (GenPop). TCSs, HDSs, and two cohorts of the Gen Pop completed the Fatigue Questionnaire (FQ) and the Hospital Anxiety and Depression Scale (HADS) as part of a questionnaire survey. Cases of CF were identified according to published cut-offs, and the levels of anxiety (HADS-A) and depression (HADS-D) were calculated. Results showed that among 791 TCSs, 16% displayed CF (HDSs, 24%; GenPop, 10%). In the age group younger than 30 years, the prevalence of CF was higher in TCSs than in the GenPop ($P < .01$). In TCSs, age, anxiety, depression, and co morbidity were independent predictors of CF. The mean HADS-A score in TCSs was significantly above the comparable figure of the Gen Pop and similar to that of HDSs. The mean HADS-D score in TCSs was below that of the Gen Pop. The highest and lowest mean scores of HADS-A and HADS-D were observed in the youngest TCSs. The study concluded that the prevalence of CF is less in TCSs than in HDSs but exceeds that of the Gen Pop. Together with co morbidity and age, anxiety and depression predict CF in TCSs,

Ourania Nicolatou-Galitis.,et al(2011) conducted a study on oral Mucositis, Pain and Xerostomia in 135 Head and Neck Cancer Patients Receiving radiotherapy with or without Chemotherapy**.** Mean total radiotherapy dose was 62.4 Gray. Chemotherapy was administered to 47% of patients. Oral mucositis was scored weekly, while patients self-evaluated

their pain and xerostomia. Cytology smears for the assessment of herpetic infection complicating the ulcers of mucositis were taken from 46 patients. Systemic antifungals and antivirals were administered during radiotherapy, upon clinical, presumptive diagnosis of candidiasis and herpetic infection. Antifungals and antivirals were continued to the end of radiotherapy. During radiotherapy, the prevalence of severe mucositis, pain and xerostomia was 57%, 43% and 29% respectively, and was significantly reduced to 33%, ($P<0.001$), to 24%,($P<0.001$), and to 18%, ($P<0.05$) at the end of radiotherapy. Antifungals and antivirals were utilized in 70% and 71% of patients, respectively. Viral cytology was positive in 14 of 46 (30.4%) patients.

Shune SE, Karnell LH, Karnell MP, Van Daele DJ,and Funk GF.,(2011) done a study on Association between severity of dysphagia and survival in patients with head and neck cancer between January 2001 and April 2003, Lowa city. Regression analyses determined factors associated with dysphagia and the association between observed survival and severity of dysphagia Almost 50% of the 407 patients had dysphagia. Risk factors included advanced stage, older age, female sex, and hypopharyngeal tumors. The most severe dysphagia which was associated with lower survival rates, was the strongest independent predictor of survival.

Lee R, Slevin N, Musgrove B, Swindell R,and Molassiotis A.,(2011) conducted a longitudinal study on prediction of post-treatment trismus in head and neck cancer patients in tertiary referral cancer centre in the United Kingdom. A total of 87 patients was studied prospectively. Results showed that 41/87 (47%) of patients presented with

trismus, 57/80 (71%) had postoperative trismus, and 41/52 (79%) had trismus 6 months after operation or radiotherapy (trismus defined as a maximum mouth opening of ≤35mm). Men and those who drank a lot of alcohol were less likely to have trismus after treatment. QOL variables showed that pain, eating, chewing, taste, saliva, social functioning, social contact, and dry mouth were significantly more impaired in the trismus group than among those without trismus. Postoperative differences in QOL between the two groups highlighted problems with social function and role-playing, fatigue, activity, recreation, and overall reduction in QOL. Women, and those who do not drink alcohol, are at particularly high risk of developing trismus.

Chaukar DA.,et al(2009) conducted a cross sectional survey on Quality of life in 212 head and neck cancer survivors. Quality of life assessments were performed using the 2 standardized health-related QOL questionnaires: The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core-30 and The Quality of Life Questionnaire Head and Neck Cancer Module. The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core-30 scores showed that the domains where most patients faired poorly included financial difficulties (54%), appetite loss (36%), fatigue (33%), and cough (30%). The Quality of Life Questionnaire Head and Neck Cancer Module scale identified the domains with poor scores to be dry mouth (64%), dental problems (42%),sticky saliva(40%), cough(39%), and problems with mouth opening (32%). Patients with early-stage tumors and those treated with surgery alone had significantly better QOL scores when compared with

advanced stage tumors and patients receiving either radiation alone or multimodality treatment, respectively.

. Abendstein H.,et al(2005) conducted a 5 year prospective study on Quality of life among 357 head and neck cancer patients from Norway and Sweden filled in HRQL questionnaires, the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 and the EORTC QLQ-H and N35, six times during the first year and then after 5 years. At 5 years, 167 (87%) of the 192 living patients filled in questionnaires. Clinical significant improvements in HRQL were not found between 1 and 5 years. Problems with teeth, opening of the mouth, dryness in the mouth, and sticky saliva were persistent or worsening. Similar findings were found regardless of sex, age, stage, or site when clinical significant changes are considered. Patients who died between 1 and 5 years reported reduced HRQL on 15 of 28 scales at 1 year compared with the survivors. Individual data showed 40% of patients reported improved global HRQL from diagnosis to 5 years after start of treatment. In addition, 11% had "top scores" at both assessment points.

Wijers.OB., Levendag.PC., Braaksma.MM., Boonzaaijer.M., Visch.LL.,and Schmitz PI.,(2002) done a study to evaluate the degree of xerostomia in 39 long-term patients with head and neck cancer survivors treated between 1965-1995 by conventional two-dimensional radiation therapy .A newly developed questionnaire and a visual analog scale (VAS) were used in analyzing the degree of dry mouth and xerostomia-related problems. The radiation dose received by the major salivary glands was estimated by analyzing two-dimensional simulation films. Sixty-four percent of the patients experienced a moderate to severe degree of xerostomia. In the multivariate analysis, three

questions regarding dry mouth, eating, and speech were particularly discriminatory for establishing the degree of xerostomia as expressed by the VAS score. In this survey, 64% of the long-term survivors, after treatment by conventional two-dimensional radiation therapy for a malignancy in the head and neck region, still experienced a moderate to severe degree of permanent xerostomia.

Hammerlid E, Silander E, Hörnestam L, and Sullivan M.,(2001) done a longitudinal study to assess the health-related quality of life (HRQL) of all head and neck cancer patients from diagnosis until 3 years later and to analyze its dependence on tumor site and other patient characteristics. Two hundred thirty-two patients (mean age 61 years; 70% men) were included and followed with clinical measures and mailed standardized HRQL questionnaires (The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core-30 (EORTC QLQ-C30), the EORTC QLQ-Head and Neck Cancer module (QLQ-H&N35), and the Hospital Anxiety and Depression Scale (HADS).After 3 years 66% of the patients were alive and 88% of these completed the study. The HRQL was worse during treatment and returned slowly thereafter to pretreatment values with few exceptions. After 3 years the best improvement was found for mental distress, followed by a significant global quality of life improvement and reduced pain compared with diagnosis. A significant deterioration was found for problems with dry mouth, senses, and teeth, as well as for opening the mouth wide (ie, they seemed to be related to the treatment given). There were few significant improvements between the 1- and 3-year follow-ups. Depression and physical functioning at diagnosis were independent predictors for global quality of life at 3 years. Patients who died

during the study had a worse HRQL at diagnosis compared with patients completing the study. Patients with advanced disease (stage III + IV) scored worse than patients with small tumors for most of the HRQL domains. These differences increased over time. Few differences were found relating to gender and age. The pharyngeal cancer group scored worse compared with the other tumor sites, and these patients would probably benefit from a rehabilitation program right from diagnosis, including treatment for malnutrition and pain. The largest HRQL changes for head and neck cancer patients are seen within the first year after diagnosis, with a significant deterioration just after finishing treatment.

Effectiveness of vegetable oil to reduce xerostomia

. Ship JA , MCcutcheon J A, Spivakosky S., and Kerr AR.,(2007) done a study on the safety and effectiveness of topical dry mouth products containing olive oil,betaine and xylitol in reducing xerostomia for polypharmacy induced dry mouth. Forty adults were entered into this single blinded open label cross clinical study and 39 completed all the visits .Subjects were randomly assigned to base line to using the novel topical dry mouth products daily for one week ,or to maintain their normal dry mouth routine care. After 1 week they were crossed over to the other dry mouth regimen. They demonstrated that the use of novel topical dry mouth products increased significantly unstimulated flow saliva rates, reduced complaints of xerostomia and improved xerostomia associated quality of life.

Walizer E M., Ephraim PM.,(2007) conducted a study on double blind cross over contolled clinical trial of vegetable oil versus xerolube

for xerostomia.The study examined the efficacy of using vegetable oil as an alternate therapy for the relief of xerostomia in patient undergoing head and neck irradiation, and showed vegetable oil is as effective as xerolube.

Doron J (2008) conducted a double blind placebo controlled prospective study on efficacy of lipid based additives (based on vegetable oil and lecithin) for treating patients with dry mouth. .Samples were allocated randomly and intervention model used for the study was parallel assignment. Patients aged between 18-90 years were eligible for the study. The study details demonstrated that there was an improvement in dry mouth symptom

Busquit M., Deasy P B.,Kelly H. M., Torrence AA., (2004) conducted a study on bioadhesive , rheological, lubricant and other aspects of an oral gel formulation intended for the treatment of xerostomia study evaluated different mucosal lubricates , as stimulants of the oral mucosa of xerostomic patients. Study found for improving the lubricity of the product optimum incorporation of vegetable oil cause a desirable lowering of the observed friction of the product.

Mouly SJ .,et al (2007) conducted a randomized control trial on Efficacy of a new oral lubricant solution in the management of psychotropic drug-induced xerostomia: The clinical efficacy and acceptability of a new oxygenated glycerol triester (OGT) (which is oxidized corn oil), oral spray (1 or 2 sprays up to 4 times daily) in the treatment of xerostomia was compared with those of a commercially available artificial saliva substitute (ASS [Saliveze]) in a 2-week, open-labeled, randomized, parallel-group study. Clinical assessment of xerostomia included evaluation of mouth dryness by

means of a 10-cm-long visual analog scale, objective blinded assessment of the oral tissue condition by a dental hygienist by means of a 4-point ordinal scale, and subjective patient-based assessment of dry mouth symptoms by means of dichotomous responses to a questionnaire. [Day 14 - baseline] patient-based mouth dryness score was the primary end point. Seventy-four patients (41 women and 33 men, 44 +/- 15 years) undergoing long-term psychotropic drug treatment were consecutively enrolled. At day 14, OGT resulted in better efficacy than ASS in mouth dryness score (mean difference, 1.2 +/- 0.4; P = 0.006), speech difficulties (mean difference, 1.2 +/- 0.4; P = 0.005), taste (mean difference, 1.1 +/- 0.4; P = 0.02), and overall mouth condition (mean difference, 1.4 +/- 0.9; P = 0.005). Taste of OGT was better than that of ASS (mean difference, 1.4 +/- 0.6; P = 0.04), as was OGT acceptability (mean difference, 1.4 +/- 0.9; P = 0.005).Oxygenated glycerol triester lubricant oral spray was superior to a commercially available ASS in improving xerostomia and overall condition of the oral tissue.

Literature related to role of nurse in reducing xerostomia

Core of nursing management is to focus on helping the patient to manage xerostomia, which include educating the patient to perform oral care. Lewis et al.,(2004) stated that saliva substitutes may be offered to patients. Oral care should be performed at least before and after each meal and at bed time. A saline solution of 1tsp of salt in 1L of water is an effective cleansing agent. One tsp of sodium bicarbonate may be added to oral solution to decrease odor alleviate pain, and dissolve mucin.

Komathy Pratheeba J(2011) conducted a quasi experimental pre-test post test two group study to assess the effectiveness of normal saline versus sodium bicarbonate mouth wash in reducing oral mucositis among patients receiving cancer treatment. Samples were selected using simple random sampling technique. Oral assessment mucositis scale used for assessing status of oral cavity .The mean post test mucositis score of experimental group -1 (16.46) who had normal saline wash was lower than the mean pre test mucositis score (19.03). the mean post test mucositis score of experimental group -2 (13.66) who had sodium bicarbonate mouth wash was lower than the mean pretest mucositis score (24.46). Both the mouth washes used for the study were effective, where sodium bicarbonate was outweighing normal saline in reducing oral mucositis.

Kendall.(2006), in his large scale qualitative specifically phenomenological study, to identify the embedded learning in the experiences of nurses caring for cancer patients in clinical practice with a research question. what is the influence of nurse patient encounters on clinical learning and practice? The data was obtained from 392 nurses by purposive sample from Australia, Bhutan and Hong Kong the data was obtained through a written exercise where by participants were given a sheet asking them to write their impressions and experiences of a care episode of a a patient with cancer. Data analysis was performed using a soft ware package (Nvivo). The themes emerged were, being brave, being nice to the nurses, putting up with pain, being in the right frame of mind, coping with difficult times, gaining spiritual support, moving toward acceptance, accepting reality. The samples are also very broad in that all the participants come from variety of clinical areas. The study brings

to the fore the learning that can occur through our rich experiences as cancer nurses along side the satisfaction through the nurse –patient relationship of caring for cancer patients.

Yvonne Wengstrom(2000) conducted a thesis on Nursing interventions in radiation therapy- Studies on women with breast cancer at Stockholm in Sweden ,A structured communication process according to the Delphi technique in three phases was used to assess perceived nursing care problems in the care of the cancer patient and in work with other professionals from the nurse's perspective. The nurses reported; poor follow-up of patients after completion of treatment, lack of time to document nursing care given and lack of time to treat patients as the most problematic areas of importance for the development of Nursing care .One hundred and thirty four patients participated in the randomized study. The experimental group consisted of 67 patients, as did the control group. No measurable effect of the nursing intervention was found for side effects or quality of life. However, the nursing intervention proved to have positive effects in minimizing stress reactions ($p =< 0.05$). Further, the results showed that the intervention provided patients older than 59 years with stronger motivation to be emotionally involved ($df=2$, $F=3.463$, $p=<0.05$).Side effects experienced the severity of the most commonly reported side effects, and quality of life during and up to three months after treatment, included analysis of the whole group ($n=134$). Experienced side effects and their severity increased as the treatment progressed. Fatigue, sleep disturbances, skin symptoms, dry mouth, sore throat, pain, nausea, cough and dyspnea were the most commonly reported side effects. Quality of life improved as treatment progressed. The women used several strategies to cope with the treatment, and

these changed over time. Family and friends had a positive impact on the coping process at all points of measurement. In addition, work and contact with colleagues provided the women with a sense of normalcy. The women used a broad spectrum of own activities to aid recovery. In conclusion, there was a significant effect of the nursing intervention on the degree of emotional involvement for patients aged over 59 years.

CHAPTER III

Research methodology

''Research methodology is a way to systematically solve the research problem. it consist of various steps that are generally adopted by a researcher in studying the problem along with the logic behind them'' (Kothari 1990)

This chapter explains about research approach, research design, the setting, sample and sampling technique, development of the tool procedure of data collection and plan for data analysis.

Research approach

The experimental study was used in this study, to determine the effectiveness of vegetable oil mouth rinsing in reduction of radiation induced xerostomia among radiation therapy patients.

Research design

This study was designed to assess the effectiveness of vegetable oil in reduction of radiation induced xerostomia among patients receiving radiation therapy.Quasi experimental pretest post test control group design was used in this study.

Schematic representation of study design is as follows:

Group	measurement of dependent variable	Manipulation of independent variable	Measurement of dependent variable	
			Post- test days	
	Pre-test		5th	10th day
experimental group	O1	X	O5	O10
control group	O1	-	O5	O10

key

O1 - pre-test among experimental and control group in terms of radiation induced xerostomia.

X - mouth rinsing by vegetable oil among patients with radiation induced xerostomia in experimental group .

O5 - post test assessment of xerostomia on 5th day in both groups

O10 - post test assessment xerostomia on 10th day in both groups.

Independent variable: vegetable oil rinsing

Dependent variable: level of xerostomia

Setting of the study

This study was conducted at Devaki cancer institute, Madurai.

Devaki cancer institute is specialized for cancer treatment which is situated around 7 km away from the sacred heart nursing college, Madurai. It has inpatient and out patient departments. On average 90 cases per day are getting radiation therapy .Out of this 40 cases are receiving radiation therapy over head and neck areas. Machine used for external radiation therapy is linear

accelerator, which generates ionizing radiation from electricity and can have multiple energies.

Population

The population for the study was patients who were receiving external radiation therapy, for cancer in head and neck areas and who had mild to moderate level of xerostomia in Groningen Radiation Induced Xerostomia questionnaire.

Sample size

The total sample size was 60.Out of which 30 patients were assigned to experimental group and 30 patients were assigned into control group.

Sampling technique

Purposive sampling technique was used for this study.

Criteria for sample selection

Inclusion criteria

The samples were selected on the following criteria..

1.Patients who were receiving external radiation therapy for cancer in head and neck areas from Devaki cancer institute Madurai during the data collection period.

2. Patient who had exposed to external radiation therapy for minimum seven sitting over head and neck areas.

3. Patient with mild(15-28) to moderate(29-42) xerostomia level in Groningen Radiation Induced Xerostomia Questionnaire.

4 .Both male and female who could communicate orally.

5. Patients who were willing to participate in the study.

Exclusion criteria

1. Patients who were on artificial saliva or lubricant application and have ulceration and fungal infections in the mouth.

2. Patients who undergone surgery in the mouth.

Research tool and technique

The tool which is used in this research study to evaluate the demographic variables, Groningen radiation induced xerostomia questionnaire and opinion questionnaire.

Tool I

It consisted demographic variables such as age sex,locality, education, occupation, nature of diet, previous history of smoking, previous history of betel nut chewing, tumor site, tumor classification, ,nature of treatment, dose of radiation therapy, and radiation therapy field.

Tool II

This consisted of Groningen Radiation Induced Xerostomia Questionnaire which is downloaded from internet on free of cost. it is a standardised tool which is developed by Ivo Beetz, Fred R Burlage, Henk P .Bijl, Hoegen Chouvalova,Miranda.E.M.CChristianenArjan Vissink,Bernard F. A.M van der Laan, Geertruida H.de Bock,Johannes A Langendijk.,(2010). This tool consist of 14 item questionnaire with four subscales: xerostomia during day and night and sticky saliva during day and night. The original relaibility of the tool using Cronbachs alpha varied for all subscales between 0.88 and 0.94, and the investigator also got similar value which shows that tool is reliable.The tool is used as it is without doing any modification.

Tool III

This consists of opinion questionnaire related to acceptance and views of samples who had experience with vegetable oil mouth rinsing. It consist of five questions which is given to experimental group on eleventh day after intervention. It had information related to satisfaction of subjects with the intervention, willingness of subjects to recommend the same intervention to others, willingness to continue the intervention after ten days, suggestion for best time to receive the intervention and opinion of subjects about the intervention in their own words. Interpretation is made using frequency distribution.

Scoring procedure

GRIX questionnaire has 14 items. Each item has 4 options ranges from 1 to 4. So the minimum score ranges from 43-54.GRIX questionnaire measures all the elements of xerostomia such as dryness of mouth and stickiness of saliva.

Normal =1-14 (1%-25%)

Mild xerostomia =15-28(26%-50%)

Moderate xerostomia=29-42(51%-75%)

Severe xerostomia=43-56(76%-100%)

Testing of the tool

Validity

To evaluate the content validity of the tool, the tool was submitted to seven experts. Five experts in the field of nursing and two experts in the field of medicine. Validated the tool based on their suggestions.

Reliability

Test retest method used for Groningen Radiation induced Xerostomia Questionnaire to find out reliability and the obtained value of r =0.94 which was highly significant. Karl Pearson's coefficient of correlation method used to find out reliability.

Development of intervention strategy

The intervention strategy was developed based on review of literature. The amount and nature of oil selected for mouth rinsing decided based on experts opinion. The intervention used for mouth rinsing annexed in appendix No.IV.

Pilot study

In order to test the feasibility of the study, pilot study was conducted among 6 subjects in the same manner as the final study. Among 6 subjects 3 assigned in the experimental group and 3 assigned in the control group. Data was analysed and the findings revealed that the study was feasible.

Data collection procedure

The study was accepted by the ethical committee in the Sacred Heart Nursing College. Following that, formal permission was obtained from the clinical oncologist in Devaki cancer institute Madurai for conducting the study.

The objectives of the study were explained to the oncologist, nursing staff and patients before starting the data collection. Level of xerostomia had been assessed for all patients who had completed seven sittings of external radiation therapy. From that patients who had mild to moderate level of xerostomia were selected purposefully.. The selected 30 samples were assigned as experimental group from Devaki cancer institute.

In experimental group, on the first day, level of xerostomia was assessed using Groningen Radiation Induced Xerostomia Questionnaire. Patients who had mild to moderate level of xerostomia were selected. After collecting pre test, the samples in experimental group received vegetable oil (sesame oil 10 ml –idhayam brand) mouth rinsing on first day from the investigator. Each sample received demonstration about the vegetable oil mouth rinsing technique, every day, then they instructed to repeat the same for two times in the home and asked to maintain a dairy indicating time for vegetable oil rinsing. The same procedure was repeated for ten days and post assessment made on 5^{th} and10^{th}day using Groningen Radiation Induced Xerostomia Questionnaire. After completing the intervention on eleventh day, the investigator obtained response of the subjects about the acceptance and views of intervention what they have received by means of opinion questionnaire related to their overall satisfaction with the intervention.

Samples for control group were also selected from Devaki Cancer Institute. Level of xerostomia was assessed using Groningen Radiation Induced Xerostomia Questionnaire and patients who had mild to moderate level of xerostomia were selected. The samples were received only the routine oral care. First day pre-test was done, and post test was made on 5^{th} and 10^{th} day using Groningen Radiation Induced Xerostomia Questionnaire. On eleventh day, samples in the control group were explained about the effectiveness of vegetable oil for relieving xerostomia in accordance with the experience of samples in the experimental group.

Plan for data analysis

The data analysis was done according to the objectives of the study by using inferential and descriptive statististics.

Descriptive statistics

Frequency, percentage and mean were used for the analysis of level of xerostomia.

Inferential statistics

1. Paired'**t** 'test was used to determine the difference between pre-test and post test in terms of effectiveness of vegetable oil mouth rinsing in experimental group.

2.Independent ' t ' test was used to determine the difference between post test of experimental group and control group in terms of effectiveness of vegetable oil rinsing.

3.Chi square was used to determine the association between selected variables.

ETHICAL CONSIDERATION

Ethical committee in the Sacred Heart Nursing College had gone thoroughly into the proposed research, assessed carefully, potential risk and possible benefit ratio to the patient and to the society .After analysing the research proposal critically, concluded that, the proposed intervention does not cause any harm to the human rights as well as it does not violate ethical rules. Since the foundation of the proposed study was in accordance with the ethical principles, the proposal got approval for conducting the pilot study and the main study.

Formal permission was also obtained from clinical oncologist and Radiologist from Devaki cancer institute Madurai.

An oral consent of each study sample was obtained before starting the data collection. Assurance was given to the patient that confidentiality will be maintained. There was absence of physical and psychological strain to study subjects.

CHAPTER - IV

ANALYSIS AND INTERPRETATION OF DATA

This chapter deals with the description of the sample, classification, analysis and interpretation of the data collected to evaluate the achievement of the objectives of the study and discussion of the study findings. The data collected is tabulated and described as follows:

Presentation of the findings of study:

Section I:

- Demographic characteristics of the sample
- Clinical profile of the sample.

Section II:

- Distribution of sample according to the level of xerostomia
- Distribution of subjects according to the level of xerostomia before and after the use of vegetable oil mouth rinsing in experimental group.
- Distribution of subjects according to the pre test & post test level xerostomia in control group.
- Distribution of subjects according to the post test level of xerostomia in experimental group and control group.

Section III:

- Comparison of vegetable oil on reduction of xerostomia
- Comparison of mean pre test and post test level of xerostomia among patients receiving radiation therapy after the vegetable oil mouth rinsing in experimental group.
- Comparison of mean pre test and post test level of xerostomia on day 5.

- ❖ Comparison of mean post test level of xerostomia on day 5 and day 10 in the experimental group.

Section IV:

- ❖ Effect of vegetable oil on reduction of xerostomia
- ❖ Comparison of mean post test level of xerostomia on day 5^{th} in the experimental group and control group.
- ❖ Comparison of mean post test level of xerostomia on day 10^{th} in the experimental group and control group.

Section V:

- ❖ Association between the level of xerostomia of experimental group with the demographic variables.

Section VI:

- ❖ Opinion questionnaire for assessment of the views of clients regarding their experience of vegetable oil mouth rinsing.

SECTION – I

Demographic Profile of the Sample:

This section deals with demographic characteristics of the subjects such as age, sex, locality, education status, occupation, nature of diet, previous history of smoking, previous history of betel nut chewing, tumor site, tumor classification, nature of treatment dose of radiation therapy and radiation therapy field.

Table 1:

Frequency and percentage distribution of the subjects with regard to selected demographic characteristics.

N = 60

Demographic Characteristics	Experimental Group n = 30		Control Group n = 30		Total	%
	f	%	f	%		
Age (in years):						
a) 30 – 40	5	16.66	1	3.33	6	10
b) 41 – 50	7	23.33	7	23.33	14	23.33
c) 51 – 60	10	33.33	20	66.66	30	50
d) 61 – 70	8	26.66	2	6.66	10	16.66
Sex:						
a) Male	24	80	27	90	51	85
b) Female	6	20	3	10	9	15
Locality:						
a) Urban	11	36.66	6	20	17	28.33
b) Rural	19	63.33	24	80	43	71.66
Education:						
a) Primary	16	53.33	5	16.66	21	35
b) Secondary	3	10	18	60	21	35
c) Higher secondary	11	36.66	7	23.33	18	30
Occupation:						

a) Farmer	14	46.66	20	66.66	34	56.66
b) Sales man	14	46.66	7	23.33	21	35
c) Coolie	2	6.66	3	10	5	8.33

The data in table 1 shows that the most of the samples 10 (33.33%) were between the 51-60 years and the least were 5 (16.66%) between 30-40 years in experimental group. In control group the highest number of samples were 20 (66.66%) were also between 51-60 years and the least were 2 (6.66%) between 61-70 years.

With regard to sex most of the samples were males 24 (80%) in experimental group where as in control group 27 (90%) were males.

Regarding locality majority of samples were from rural area in experimental group 19 (63.33%) as well as control group 24 (80).

With regard to educational status most of them 16 (53.33%) were studied up to primary education in experimental group and in control group majority of patients had secondary level of education 18 (60%).

With regard to occupation, majority of samples were farmers and salesman 14 (46.66%) in experimental group and in control group majority of samples were farmers 20 (66.66%).

Table 2: **Clinical profile of the sample**

N=60

Clinical profile	Experimental Group n = 30		Control Group n = 30		Total	%
	f	%	f	%		
Nature of Diet:						
a) Liquid	17	56.66	25	83.33	42	70
b) Semisolid	13	43.33	5	16.66	18	30
c) Solid	-	-	-	-	-	-
Previous history of smoking:						
a) No	16	53.33	7	23.33	23	38.33
b) Yes	14	46.66	23	76.66	37	61.66
Previous history of betel nut chewing:						
a) No	4	13.33	10	33.33	14	23.33
b) Yes	26	86.66	20	66.66	46	76.66
Tumor Site:						
a) Head	19	63.33	12	40	31	51.66
b) Neck	11	36.66	18	60	29	48.33
Tumor Classification:						
a) $T_3N_0M_0$	24	80	24	80	48	80
b) $T_4N_1M_0$	6	20	6	20	12	20
Nature of Treatment:						
a) Surgery	2	6.66	6	20	8	13.33
b) Chemotherapy	30	100	30	100	60	100
c) Radiation – 15^{th} day	7	23.33	13	43.33	20	33.33
- 16^{th} day	7	23.33	10	33.33	17	28.33
- 17^{th} day	13	43.33	5	16.66	18	30
- 20^{th} day	3	10	2	6.66	5	8.33
Dose of Radiation/day						
a) 200 centigray	30	100	30	100	60	100

Table cont…

Demographic Characteristics	Experimental Group n = 30		Control Group n = 30		Total	%
	f	%	f	%		
Radiation therapy field:						
a) Oral cavity	12	40	5	16.66	17	28.33
b) Oro phargnx	3	10	5	16.66	8	13.33
c) Whole neck	14	46.66	20	66.66	34	56.66
d) Pituitary neck	1	3.33	-	-	1	1.66

Data in table 2 portray that with regard to nature of diet, majority of samples in experimental group 17 (56.66%) and control group 25 (83.33%) were taking liquid diet during radiation.

Regarding previous history of smoking, majority of samples in experimental group 76 (53.33%) had no history of smoking where as in control group majority of samples 23 (76.66%) had history of smoking.

With regard to previous history of betel nut chewing majority of samples in experimental group 26 (86.66%) and control group 20 (66.66%) had the history of betel nut chewing.

With regard to tumor site majority of samples in experimental group 19 (63.33%) have been suffering from tumor in the head where in control group 18 (66%) majority of samples have been suffering from tumor in the neck region.

Regarding tumor classification, majority of samples in experimental group 24 (80%) and in control group 24 (80%) were in $T_3N_0M_0$ tumor classification.

With regard to nature of treatment, 2 (6.66%) samples had undergone surgery in experimental group and in control group 8 (13.33%) samples had undergone

surgery. Both samples in experimental group and control group had finished chemotherapy.

Regarding the dose of radiation therapy both samples from experimental group and control group were receiving radiation dose of 200 centigray.

With regard to radiation therapy field, majority of samples in experimental group 14 (46.66%) as well as in control group 20 (66.66%) were receiving radiation on the whole neck region.

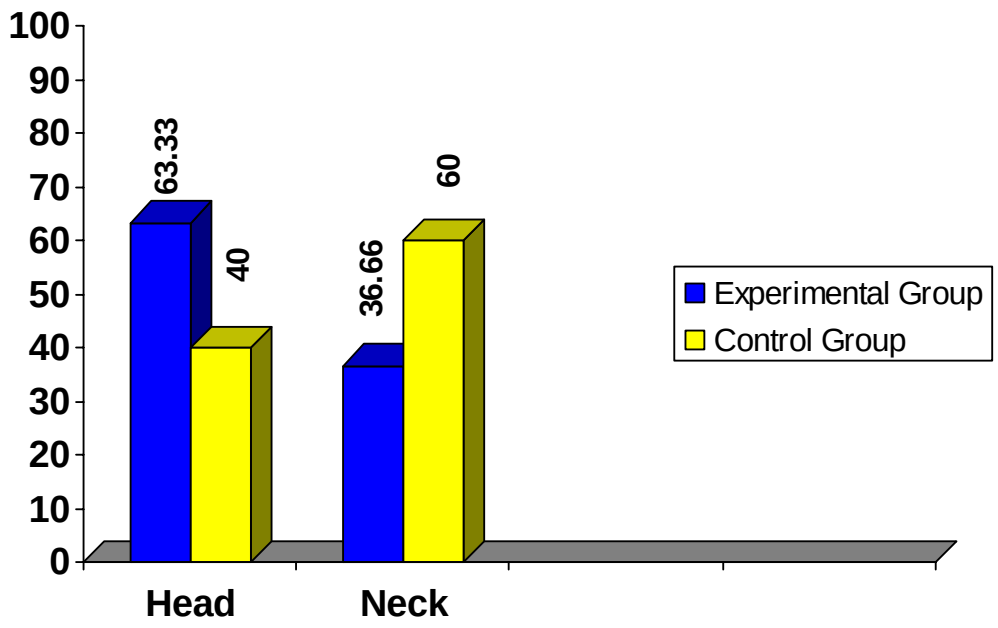


Figure 2: **Distribution of subjects in experimental group and control group in terms of Tumor site**

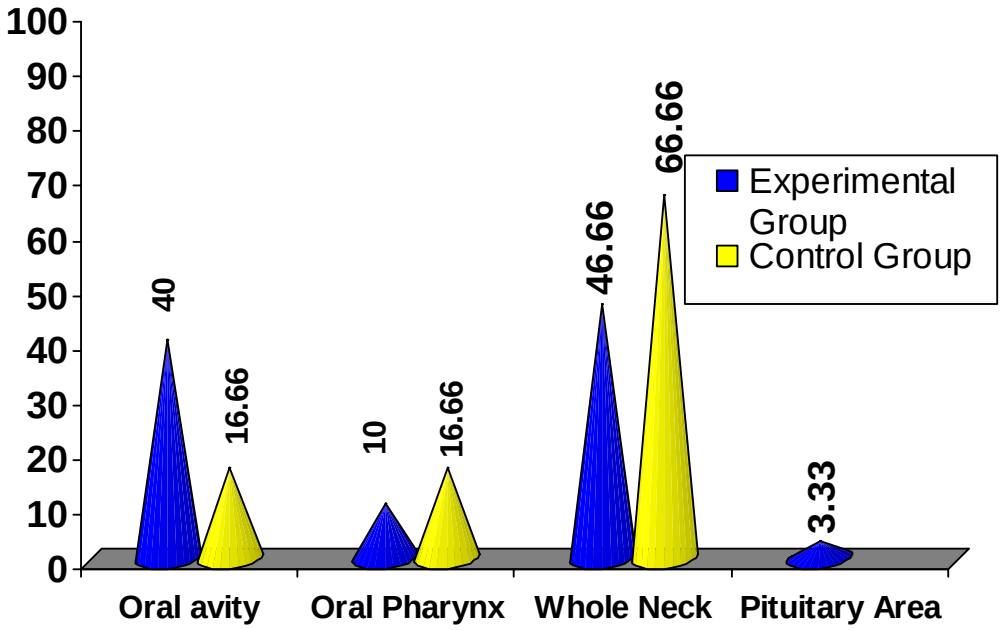


Figure 3: **Distribution of subjects in experimental group and control group in terms of Radiation therapy field**

SECTION – II

Distribution of sample according to the level of Xerostomia.

Table 3:

Distribution of subjects according to the level of xerostomia before and after the use of vegetable oil in experimental group.

N = 30

Level of Xerostomia	Experimental Group					
	Pre Test		Post Test			
			5th		10th	
	f	%	f	%	f	%
Normal	-	-	-	-	24	80%
Mild	-	-	30	100	6	20%
Moderate	30	100	-	-	-	-
Severe	-	-	-	-	-	-

Data on table-3 is based on the xerostomia level obtained. The subjects were classified under 4 groups. Normal (1-14), mild (15-28), moderate (29-42), severe (43-56). A higher score indicates poor xerostomia status, where as a low score indicates reduction in xerostomia level.

Table 3 shows that before vegetable oil mouth rinsing 30 (100%) samples had moderate level of xerostomia. After vegetable oil mouth rinsing, on 5th day 30 (100%) samples had mild level of xerostomia, on 10th day 24 (80%) samples had normal level of xerostomia and 6 (20%) samples had mild level of xerostomia. This difference in the level of xerostomia may be due to the effect of vegetable oil mouth rinsing.

Table 4:

Distribution of subject according to the pre and post test level of xerostomia in control group

N=30

Level of Xerostomia	Control Group					
	Pre Test		Post Test			
			5th day		10th day	
	f	%	f	%	f	%
Normal	-	-	-	-	-	-
Mild	28	93.3	-	-	-	-
Moderate	2	6.6	30	100	-	-
Severe	-	-	-	-	30	100

Data on table 4 shows that 28 (93.3%) of samples had mild level of xerostomia & 2 (6.6%) had moderate level during pre test in control group. All the samples in control group had moderate & severe level of xerostomia on 5th & 10th day of post test.

Table 5:

Distribution of subjects according to the post test level of xerostomia in experimental group and control group.

N = 60

Level of Xerostomia	Experimental group n = 30				Control group n = 30			
	5th		10th		5th		10th	
	f	%	f	%	f	%	f	%
Normal	-	-	24	80	-	-	-	-
Mild	30	100	6	20	-	-	-	-
Moderate	-	-	-	-	30	100	-	-
Severe	-	-	-	-	-	-	30	100

Data on table 5 show that 24 (80%) of samples had normal level of xeroxtomia on 10th day of post test in experimental group where as in control group all the samples 30 (100%) had severe xerostomia. All the samples 30 (100%) had mild level of xerostomia in experimental group where as in control group all the samples 30 (100%) had moderate level of xerostomia.

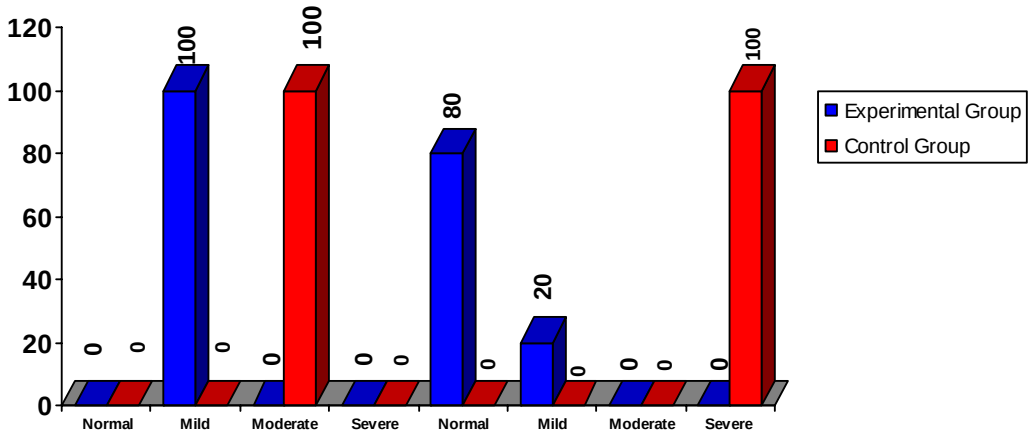


Figure 4: **Distribution of subjects according to the post test level of Xerostomia on 5th and 10th day in experimental group and control group**

SECTION – III

Comparison of vegetable oil mouth rinsing on reduction of xerostomia.

Table 6:

Comparison of mean pre test and post test level of xerostomia among patients receiving radiation therapy after the vegetable oil mouth rinsing in experimental group. N=30

Measurement	N	Mean	SD	t = value
Pre test	30	34.566	1.62	66.19*
Post test	30	14.2	0.4	

* Significant at 0.05 level.

To find out if there is any difference between the mean level of xerostomia before and after the use of vegetable oil mouth rinsing, the null hypothesis was stated as follows

H_{01}:

The mean post test level xerostomia in experimental group who received vegetable oil mouth rinsing will not be significantly lower than their mean pre test xerostomia level.

Data on table 6 shows that the mean post test level of xerostomia is (14.2) after the use of vegetable oil moth rinsing was lower than the mean pre test xerostomia (34.566). The obtained‘t’ value of 66.19 at df (2.042) was significant at 0.05 level. This indicates that the difference has not occurred by chance. So the researcher rejects the null hypothesis and accepts the research hypothesis.

The above findings imply that the vegetable oil mouth rinsing has a significant effect in reducing the level of xerostomia of samples.

Table 7:

Comparison of mean pre test and post test level of xerostomia in experimental group on day 5.

N =

				30
Measurement	**N**	**Mean**	**SD**	**t= value**
Pre test	30	34.56	1.62	
				30.467*
Post test	30	23.766	1.44	

* Significant at 0.05 level.

Data on table 7 shows that the mean level of xerostomia on day 5 (23.76) after the use of vegetable oil mouth rinsing was lower than the pre test level of xerostomia (34.56). The obtained‘t’ value of 30.467 at df (2.042) was significant at 0.05 level. This indicates that the difference between mean (10.8) was a true difference and has not occurred by chance.

The above findings imply that the vegetable oil mouth rinsing has a significant effect in reducing the level of xerostomia of patients with radiation therapy for cancer.

Table 8:

Comparison of mean post test level of xerostomia on day 5 and day 10 in the experimental group.

N = 30

Measurement	N	Mean	SD	t = value
Level of xerostomia on day 5	30	23.76	1.44	34.976*
Level of xerostomia on day 10	30	14.2	0.4	

* Significant at 0.05 level.

Data on table 8 shows that the mean level of xerostomia on day 10^{th} (14.2) after the use of vegetable oil mouth rinsing is lower than the level of xerostomia on day 5 (23.76). The obtained't' value of 34.976 at df (2.042) was significant at 0.05 level. This indicates that the difference between the means (9.56) was a true difference and has not occurred by chance.

The above findings imply that the continuous use vegetable oil mouth rinsing has a significant effect in reducing xerostomia in patients with radiation therapy for cancer.

SECTION – IV

Effect of vegetable oil mouth rinsing on reduction of xerostomia.

Table 9: **Comparison of mean post test level of xerostomia of the experimental group and control group on day 5.**

N = 60

Measurement	N	Mean	SD	t = value
Experimental group	30	23.766	1.44	27.388*
Control group	30	38.2	2.533	

* Significant at 0.05 level.

To find out if there is any difference between the mean post test level of xerostomia after the use of vegetable oil mouth rinsing in experimental group and control groups, the null hypothesis was stated as follows:

H_{02}:

The mean post test xerostomia level among patients in experimental group on day 5 will not be significantly lower than the mean post test level xerostomia among patients in control group on day 5

Data on table 9 shows that the mean level of xerostomia in experimental group on 5^{th} day (23.76) after the use of vegetable oil mouth rinsing is lower than the mean post test xerostomia level of the control group (38.2). The obtained 't' value of (27.38) at df (2.000) is significant at 0.05 level. This indicates the difference between mean (14.44) is a true difference and has not occurred by chance. So the researcher rejects the null hypothesis and accepts the research hypothesis.

Therefore it can be concluded that the vegetable oil mouth rinsing has been an effective method in decreasing the xerostomia level in the experimental group.

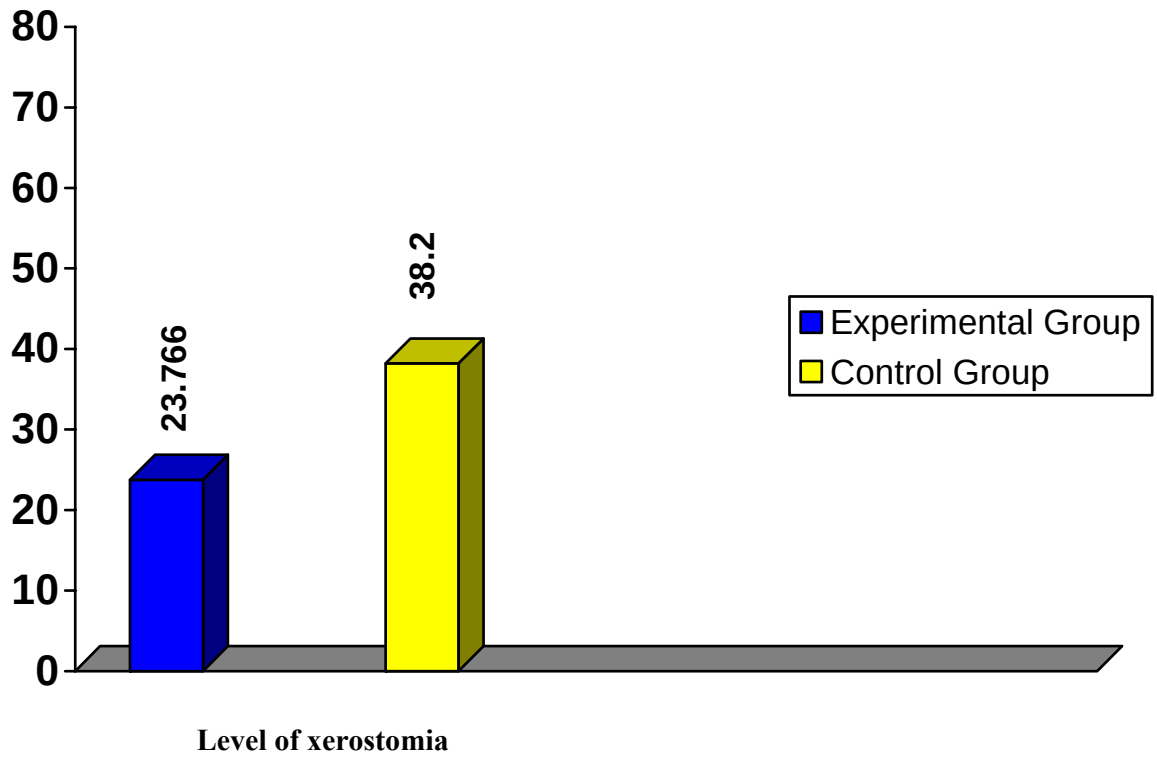


***Figure 5*: Comparison of post test mean level of Xerostomia in experimental group and control group on day 5**

Table 10:

Comparison of mean post test level xerostomia of experimental group and control group on 10th day.

N = 60

Measurement	N	Mean	SD	t = value
Experimental group	30	14.2	0.4	
				57.00*
Control group	30	43.766	2.838	

* Significant at 0.05 level.

Data on table 10 shows that the mean post test level of xerostomia in the experimental group (14.2) after the use of vegetable oil mouth rinsing is lower than the post test mean level of control group (43.766). The obtained 't' value of 57.00 at df (2.000) indicates that the difference between the mean 29.566 is a true difference and has not occurred by chance.

Therefore it can be concluded that the vegetable oil mouth rinsing has been an effective method in decreasing the xerostomia level in the experimental group.

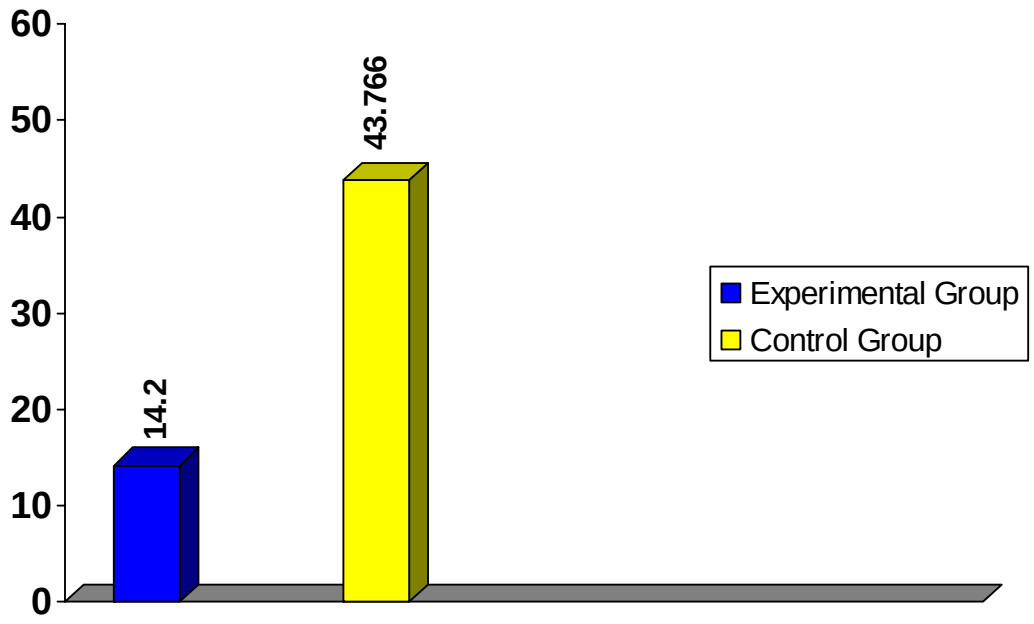


Figure 6: **Comparison of mean post test level of Xerostomia in experimental group and control group on 10th day.**

SECTION – V

Table 11:

Association between the levels of xerostomia of the experimental group after the use of vegetable oil mouth rinsing with demographic variables.

N = 30

Variables	Level of Xerostomia		
	Below mean	**Above mean**	**χ^2 Value**
Age (in years):			
a) 30 – 40	4	1	
b) 41 – 50	6	1	
c) 51 – 60	8	2	0.2677#
d) 61 – 70	6	2	
Education:			
a) Primary	12	4	
b) Secondary	3	0	
c) Higher secondary	9	2	1.0225#
Locality:			
a) Urban	8	3	
b) Rural	16	3	0.5741#
Tumor classification:			
a) $T_3N_0M_0$	20	4	
b) $T_4N_1M_0$	4	2	0.8323#
Site of Tumor:			
a) Head	13	6	
b) Neck	11	0	4.342*
Radiation Field:			
a) Oral cavity	9	3	
b) Oropharynx	3	0	
c) Neck	12	2	5.225#

Table cont…

Variables	Level of Xerostomia		
	Below mean	Above mean	χ^2 Value
d) Pituitary Area	0	1	
Previous History of Smoking:			
a) No	2	14	
b) Yes	4	10	1.291#
Betal Nut Chewing:			
a) No	2	2	
b) Yes (20-30)	7	4	
c) Yes (31-40)	13	0	8.8635*
d) Yes (41-50)	2	0	

Not significant at 0.05 level

* Significant at 0.05 level.

H_{03}:

There will be no association between the level of xerostomia after the use of vegetable oil mouth rinsing and selected variables (age, education, tumor classification, site of tumor, field, previous history of smoking, betel nut chewing and tobacco use).

In order to find out the association between the level of xerostomia after the use of vegetable oil mouth rinsing and selected variables, chi-square test is computed. There was no association found between xerostomia and age as the obtained chi-square value was 0.2677 at 3 df (7.82).

Regarding the level of xerostomia and education the calculated value was 1.0225 at 2 df 5.99.

It is found that there is no association between locality and xerostomia, the obtained chi-square value was 0.5741 at 1 (3.84).

It is found that there is no association between tumor classification and xerostomia, the obtained chi-square value was 0.8323 at 1 df (3.84).

It is found that there is an association between site of tumor and xerostomia, with the obtained chi-square value is 4.342 at 1 df 3.84.

Regarding the level of xerostomia and radiation field the calculated value was 5.225 at 3 df (7.82) and it was not significant at 0.05 level.

It is found that there is no significant association between the level xerostomia and previous history of smoking with the obtained chi-square value is 1.291 at 1 df (3.84).

It is found that there is an association between the level of xerostomia and betel nut chewing with the obtained chi-square value 8.8635 at 3 df (7.82).

This may be inferred that vegetable oil mouth rinsing is effective in reducing xerostomia with the influence of site of tumor, history of smoking, betel nut chewing, and without the influence of age, education, locality, tumor classification and radiation field.

SECTION – VI

Opinion questionnaire for assessing the views of the clients regarding their experience of vegetable oil mouth rinsing.

Table 12: **N = 30**

1.	What do you feel about the intervention you have received	**Satisfied**		**Not Satisfied**		**No Opinion**	
		n	**%**	**n**	**%**	**n**	**%**
		30	100	-	-	-	-
2.	Will you recommend same intervention to your friends who is having similar problems.	**Yes**		**Those who said yes Reasons**		**No**	
		f	**%**	**f**	**%**	**f**	**%**
		30	100	1. Feels good 14 46.6 2. Others will be benefited 16 53.3		- -	- -
3.	Will you continue the intervention even after ten days.	**Yes**		**Reason for Yes**		**No**	
		f	**%**	**f**	**%**	**f**	**%**
		30	100	1. Reduces discomfort due to stickiness & dryness 5 16.66		-	-

Table cont….

3.	Will you continue the intervention even after ten days.	**Yes**		**Reason for Yes**		**No**	
		f	**%**	**f**	**%**	**f**	**%**
		30	100	2. Comfortable feels fresh, smooth clean and keeps mouth moist. 22 73.3 3. Promotes easiness to have food 3 10		-	-
4.	Give suggestion regarding right time for receiving intervention	**Before food**		**After food**			
		f	**%**	**f**			**%**
		25	83.3	5			16.6
5.	Give opinion in your words about the intervention what you have received	Opinions					
		f		**%**			
		1. Reduces stickiness and dryness 23 76.66 2. Reduces intake of water during food 4 13.33 3. Cleanses and keeps mouth moist 3 10					

Data on table 12 shows that 100% of samples satisfied with the experience of vegetable oil mouth rinsing.

It also shows that 100% of samples were willing to recommend the same intervention to their friends.

It shows that 30 (100) of samples would continue the intervention after ten days 22 (73.33%) samples felt comfortable, and 5 (16.66%) samples were willing to

continue because of reduced stickiness and dryness of mouth 3 (10%) samples are willing to continue the intervention because of easiness to have food.

25 (83.3%) samples suggested, the right time for receiving intervention was before food and 5 (16.66%) samples suggested it as after food.

23 (76.66%) samples gave opinion regarding the intervention as it reduces stickiness and dryness. 4 (13.33%) samples expressed that as it reduces the intake of water during food, and 3 (10%) samples opinioned as it cleanses and keep mouth moist.

CHAPTER V

DISCUSSION

This study was conducted to evaluate the effectiveness of vegetable oil on reduction of radiation induced xerostomia among patients receiving radiation therapy at a selected hospital in Madurai .This study was conducted among patients with head and neck cancer who were undergoing radiation therapy. The tool used for study was Groningen Radiation Induced Xerostomia Questionnaire.

The study findings are discussed in this chapter with reference to the objectives and hypotheses as stated in chapter -I

MAJOR FINDINGS OF THE STUDY

Demographic characteristics of the samples

With regard to age, in both experimental group and control group majority of samples were between 51-60years, 10(33.33%) and 20(66.66%) respectively.

Regarding sex, in both the experimental group and control group the majority of the samples were males. 24(80%) in experimental group and 27(90%) in control group respectively.

With regard to locality both in experimental group and control group majority of samples were from rural areas. 19(63.33) in experimental group and 24(80%) in control group respectively.

Regarding educational status majority of samples in experimental group 16(53.33%) were studied up to primary education where as in control group 18(60%) had secondary level of education.

With regard to occupation, majority of samples were farmers 14(46.66%) and salesman 14(46.66%) in experimental group where as in control group majority of samples were farmers only (66.66%).

Regarding nature of diet both in experimental group and control group majority of samples were taking liquid diet during radiation.

With regard to previous history of smoking, majority of samples in experimental group 16(53.3%) had no history of smoking where in control group majority of samples 23(76.66) had history of smoking.

Regarding previous history of betel nut chewing and tobacco use ,both in experimental group and control group had the history of betel nut chewing and tobacco use 26(86.66%) and 20(66.66%) respectively

With regard to tumour site majority of samples in experimental group 19(63.33%) have been suffering from tumour in head where in control group 18(66%) samples have been suffering from tumour in the neck region.

b) Regarding tumour classification both in experimental group and control group majority of samples were in $T_3N_0M_0$ tumour classification 24(80%).

With regard to nature of treatment 2(6.66%) samples had undergone surgery in experimental group where as in control group 8(13.33%) samples had undergone surgery. Both samples in experimental and control group had finished chemotherapy. Majority of samples in experimental group 13(43.33%) had finished 17 sittings where as in control group 13(43.33%) had finished 15 sittings.

Regarding the dose of radiation therapy both in experimental group and control group were receiving radiation dose of 200centigray.

With regard to radiation therapy field both in experimental group and control group were radiation on the whole neck region14 (46.66%) and 20(66.66%) respectively.

The above data shows that experimental group and control group were similar in forms of some of the demographic variables such as age, sex, locality, nature of diet, previous history of betel nut chewing and tobacco use.

Distribution of subjects according to the level of xerostomia before and after the use of vegetable oil in experimental group.

Data in table -3 portray that all the subjects 30(100%) had moderate level of xerostomia before the use of vegetable oil, where as after the use of vegetable oil all the subjects had mild level of xerostomia on 5th day of post test and normal 24(80%) as well as mild 6(20%) level of xerostomia on 10th day of post test.

Distribution of subjects according to the pre-test and post test level of xerostomia in control group.

Table-4 shows that majority of subjects 28(93.3%) had mild level of xerostomia in control group during pre-test where as in post test all the subjects had moderate and severe level of xerostomia on 5th and 10th day respectively.

Distribution of subjects according to the post test level of xerostomia in experimental group and control group.

Data on table 5 shows that in experimental group all the subjects 30(100%) had moderate level of xerostomia. In experimental group majority of subjects 24(80%) had normal level of xerostomia on 10th day of post test, where as in control group all the subjects 30(100%) had severe level of xerostomia.

Comparison of mean pretest and post test level of xerostomia among patients receiving radiation therapy after the vegetable oil mouth rinsing in experimental group.

Data on table 6 shows that the mean post test level of xerostomia (14.2) after the use of vegetable oil mouth rinsing was lower than the mean pre-

test level of xerostomia(34.566%) before the use of vegetable oil. The obtained t value is greater than the table value. This indicates that the vegetable oil mouth rinsing is effective in reducing xerostomia.

The present study findings are supported by bala Seetharaman,Ananthakumari Rajan,Beula Premkumar ,Faith Rangad D.V.,(2000) findings. They conducted double blinded randomized cross over controlled study on efficacy of vegetable oil and wet mouth solution in reduction radiation induced xerostomia of patients with head and neck cancer who received radiation therapy. Randomization was done to distribute the therapies (vegetable oil therapy and wet mouth solution).the sample size was sixty. Data collection was carried out for six weeks. Each therapy was administered three times a day for two days on the third and sixth day. The investigator evaluated the effectiveness of therapy. Results showed there was improvement of xerostomia related problems with vegetable oil speech (100%) stickiness of throat (100%) salivation (51.6), thickening of saliva (75%) swallowing (57.9%),insomnia (85.4%) taste (76.5%) food intake (51.2%).with wet mouth solution speech (95%) stickiness of throat (92.3%) salivation (53.4%), thickening of saliva (73.3%) swallowing (57.9%),insomnia (78%) taste (64.7%) food intake (46.5%). There was statistically no significant difference between both the therapies in relieving the xerostomia related problems.

Comparison of mean pre-test and post test level of xerostomia in experimental group on day 5.

Data on table 7 portray that the mean post test level of xerostomia on day 5th(23.766%) in experimental group was lower than the mean pretest level of xerostomia(34.56). the t value of 30.46 at df (2.042) is significant at 0.05 level/ these findings revealed that vegetable oil mouth rinsing is effective for reducing xerostomia.

Comparison of mean post test of xerostomia of the experimental group and control group on day 5.

Data on table 9 shows that the mean level of xerostomia in experimental group 23.766 on day 5 after the use of vegetable oil is lower than the post test level mean of xerostomia in the control group (38.2).The obtained t value of 37.388 at df (2.000) is significant at 0.05 level. These findings revealed that vegetable oil mouth rinsing is effective in reducing xerostomia.

Comparison of mean post test level xerostomia of experimental group and control group on 10th day.

Data on table 10 shows that the post test level of xerostomia in experimental group (14.2) on day 10th is lower than the mean post test level of xerostomia in control group (43.766).the obtained t value of 57.00 is greater than the table value. It indicates that after after doing vegetable oil mouth rinsing for continuous ten days, there has been significant reduction in the xerostomia level among patients with radiation therapy.

Association between the level of xerostomia of the experimental group after the use of vegetable oil mouth rinsing and selected demographic variables (age, education, locality, tumour

classification, site of tumour, radiation field, previous history of smoking and tobacco and betel nut chewing)

Data on table 11 shows that in order to find out the association between the level of xerostomia reduction and selected variables such as 1.age chi square value 0.2677 at 3 df (7.82) p(< 0.05) 2. education chi square 1.0225 at 2 df (5.99) p(< 0.05) 3.locality chi square 0.5741 at 1 df (3.84) p(< 0.05) 4. tumor classification chi square 0.8323 at 1 df(3.84) 5. radiation field chi square 5.225 at 3 df (7.82) p (< 0.05) 6. previous history of smoking chi square 1.291 at 1 df (3.84) p (< 0.05).It was found that there was an association between xerostomia and selected variables such as 1. tumour site chi square 4.344 at 1 df (3.84) p (>0.05) at 3 df (7.82) 2. tobacco and betel nut chewing chi square 8.8635 at 3 df (7.82) p (>0.05).

The present study findings are supported by Dikshit RP and Kanhere S.,(2000) They conducted a case control study on Tobacco habit and risk of lung , oropharyngeal and oral cavity cancer in Bhopal, India. In all 163 lung, 247 oropharyngeal and 148 oral cavity cancer cases from the Population-Based Cancer Registry records, and 260 controls randomly selected from a tobacco survey conducted in the Bhopal population formed the study population. A significant risk of bidi and cigarette smoking with a dose response relationship was observed for lung and oropharyngeal cancer. Tobacco quid chewing showed no risk for lung, marginally increased risk for oropharyngeal and about a six fold increased risk for oral cavity cancer. Population-attributable risk percent (PARP) was 82.7% and 71.6% for smokers for development of lung and oropharyngeal cancer, while the same was found to be 66.1% for tobacco chewers for the development of oral cavity cancer.

These data provide strong evidence that smoking bidiis is even more hazardous than cigarette smoking in the development of lung and oropharyngeal cancer.

CHAPTER VI

Summary, conclusion, implications, and recommendations.

This chapter presents the summary, major findings, conclusion, implication and recommendations of the study.

Summary

The aim of the study was to determine the effectiveness of vegetable oil in reduction of xerostomia among patients with radiation therapy for head and neck cancer treatment with mild to moderate level of xerostomia.

The following **objectives** were set of the study.

- To determine the level of xerostomia among patients in experimental group before and after vegetable oil mouth rinsing.
- To find out the pre-test and post test level of xerostomia among patients in control group.
- To compare the post test level of xerostomia among the experimental group and control group.
- To find out the effectiveness of vegetable oil in reducing xerostomia among subjects in experimental group.
- To find out the association between the post test level of xerostomia of experimental group with selected variables (age, education, locality, tumour classification, site of tumour, radiation field, previous history of smoking, previous history of betel nut chewing and tobacco use)

The following **hypotheses** were set for the study, all hypotheses were tested at 0.05 level of significance.

. H1- The mean post test level xerostomia on day in experimental group who received vegetable oil mouth rinsing will be significantly lower than their mean pre-test xerostomia level.

.H2-The mean post test xerostomia level among patients in experimental group will be significantly lower than the mean post test xerostomia level among patient with radiation therapy in the control group

H3- There will be a significant association between the post test level of xerostomia among patients with radiation therapy in the experimental group and selected demographic variables (age, education, locality, tumour classification, site of tumour, nature of treatment, radiation field, and previous history of smoking, betel nut chewing and tobacco use)

Major findings of the study

1.Characteristics of the samples

1.1With regard to distribution of age there were many subjects 33.33% between the age of 51-60 years in experimental group where in control group 66.66% between the age of 51-60 years.

1.2 Regarding sex 80% of subjects were males in experimental group and 90% subjects were males in control group.

1.3 With regard to locality 63.33% of subjects in experimental group from rural areas and in control group 80% of subjects were from rural areas.

1.4 With regard to educational status 53.33% were studied up to primary education, 10%were studied up to secondary education and 60%were studied up to secondary education, 23.33%were studied up to higher secondary education.

1.5 With regard to occupation 46.66% were farmers and sales man (46.66%) in experimental group where as in control group 66.66% were farmers

1.6 It was found that 56.66% in experimental group and 83.33%in control group were taking liquid diet during radiation therapy.

1.7 With regard to previous history of smoking 53.33% had no previous history of smoking in experimental group where as in control group 46.66% had previous history of smoking.

1.8 It was found that 86.66% in experimental group and 66.66% in control group had previous history of betel nut chewing and tobacco use.

1.9 Regarding the type of tumour 63.33% of subjects had tumour in the head where as in control group 60% of subjects had tumour in the neck region.

1.10 It was found that 80% in experimental group and 80% in control group were classified under $T_3N_0M_0$ tumour classification.

1.11 With regard to nature of treatment in terms of surgery, chemotherapy, and radiation therapy 6.66% in experimental group and a 13.33% in control group had undergone surgery. All the subjects in experimental group and control group had finished chemotherapy. 43.33% of samples in experimental had finished 17 sittings of radiation therapy where as in control group 43.33% of samples had finished 15 sittings of radiation therapy.

1.12 It was found that both experimental group and control group samples were receiving 200 centigray of radiation dose per day.

1.13 It was found that 46.66% in experimental group and 66.66%in control group were receiving radiation therapy in the whole neck region.

2. Comparison of mean pre-test and post test level of xerostomia among patients receiving radiation therapy after the vegetable oil mouth rinsing in experimental group.

The mean post test level of xerostomia (14.2) after the use of vegetable oil mouth rinsing was lower than the mean pre-test level of xerostomia (34.566) before the use of vegetable oil in experimental group. The obtained't' value of 66.19 at df (2.042) was significant at 0.05 level.

3. Comparison of mean post test level of xerostomia of xerostomia of experimental group and control group on 10th day.

The mean post test level of xerostomia in experimental group (14.2) is lower than the mean post test level of xerostomia in control group (43.766). The obtained't' value of (57.00) at df (2.000) was significant at 0.05 level.

4. Association between post test level of xerostomia in experimental group and selected variables.

4.1 There was a significant association between reduction in the level of xerostomia and selected variables (site of tumour, and previous history of tobacco and betel nut chewing)

There was no significant association between reduction in the level of xerostomia and selected variables (age, education, locality tumour classification and previous history of smoking)

Conclusions

The following conclusions were drawn from the study

1. The level of xerostomia of patients who received radiation therapy for head and neck cancer treatment decreased after vegetable oil mouth rinsing.

2. Continuous vegetable oil mouth rinsing decreases the level of xerostomia.

3. The study found that there was an association between the level of xerostomia and selected variables (tumour site, previous history of tobacco and betel nut chewing).

4. The study found that there was no association between reduction in the level of xerostomia and selected variables (age, education, locality, tumour classification, radiation field and previous history of smoking)

5. Opinion which is obtained from the samples in experimental group reiterate that they are comfortable with vegetable oil mouth rinsing.

Implications

This study has many implications in the field of nursing. This includes nursing practice, nursing education, and nursing research.

Nursing practice

1. The findings of the study enlighten the fact that the vegetable oil mouth rinsing can be used to reduce the level of xerostomia among patients receiving radiation therapy for head and neck cancer treatment.

2. Vegetable oil has lubricating and moisturizing effect on oral mucosa. It improves the oral health. Since nurses have got the responsibility to improve QOL of patients. The therapy is useful in ward settings.

3. Nursing personnel are in the best position to implement the vegetable oil mouth rinsing to different clients who are experiencing xerostomia.

4. Vegetable oil mouth rinsing can be used to reduce the level of xerostomia among different group of patients.

Nursing education

1. Conducting in service education on management of xerostomia for nurse will help them to update their knowledge.

2. Emphasis must be given in the nursing management regarding the use of vegetable oil mouth rinsing to reduce xerostomia.

Nursing administration

1. Necessary in service education is to be provided to the nursing personnel to make them aware of vegetable oil mouth rinsing in hospital set up to decrease xerostomia among radiation therapy and chemotherapy patients
2. Update the clinical nurse's knowledge about vegetable oil mouth rinsing through workshop, conferences to reduce the xerostomia and thereby improve the quality of life of patients with radiation induced xerostomia.
3. Nurse administrator can insist the use of vegetable oil mouth rinsing in clinical practice.

Nursing research

1. Extensive research must be conducted to identify effectiveness of vegetable oil mouth rinsing among patients receiving radiation therapy for head and neck cancer treatment.

2. This study can be a baseline for further studies to build upon.

Limitations

The limitations of the study were as follows.

1. The study was limited to patients who have undergone radiation therapy for head and neck cancer at Devaki cancer institute during data collection period.

2. The sample size was only 60, so the findings could be generalized with cautions.

3. The subjects who had mild to moderate level of xerostomia during the data collection were selected purposefully.

4. The study period was limited to six weeks

5. The vegetable oil mouth rinsing was implemented only for patients who are receiving radiation therapy.

Recommendations

On the basis of present study following recommendations are made

1. The study could be replicated by taking larger samples.

2. Comparative study could be conducted to find out effectiveness of vegetable oil with other over the counter medications in reduction of radiation induced xerostomia.

3. Experimental study can be conducted with vegetable oil for reducing other radiation induced complications like mucositis, oral ulcer etc.

4. Study could be carried out by increasing other variables like improvement quality of life after vegetable oil mouth rinsing who have undergone for radiation therapy and chemotherapy.

5. A similar study could be conducted on a longitudinal basis.

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APPENDIX-I

Letter requesting opinion and suggestion of experts for content validity of Groningen Radiation Induced Xerostomia Questionnaire

From

II Yr, M.Sc.,(Nursing)
Sacred heart College of Nursing,
Madurai -20.

To

Dear Madam /Sir,

Sub: Requesting opinion and suggestion of experts for content validity of Tool-reg;.

I am---------- a final year M.Sc.,(N) student in Sacred Heart Nursing College. In partial fulfillment of Master degree in Nursing, I have selected the topic mentioned below for the research project to be submitted to the Dr.M.G.R. Medical University, Chennai.

Problem Statement

"A quasi experimental study to assess the effectiveness of vegetable oil in reduction of radiation induced xerostomia among patients receiving radiation therapy at a selected Hospital in, Madurai"

Enclosed here with the Groningen Radiation Induced Xerostomia Questionnaire . May I request you to kindly validate Groningen Radiation Induced Xerostomia Questionnaire against the enclosed evaluation criteria and give your expert opinion for necessary modification for the same.

Enclosure

- Demographic profile
- Groningen Radiation Induced Xerostomia Questionnaire

Thanking you in anticipation,

Place: Madurai
Date:

Yours Sincerely,

APPENDIX - II

List of experts consulted for the content validity of Research tools

1. Dr.Amarnath., M.D, DMRT, MBA**.,**

Senior Consultant Clinical & Radiation Oncologist

Apollo Speciality Hospital,

Madurai.

2. Dr. K.S Krishna Kumar

Senior Consultant (Radiation Oncology)

Meenakshi Mission Hospital

Madurai.

3. Dr Nalini Jayavanth Santha, M.Sc.,(N) Ph.D.

Principal

Sacred Heart Nursing College,

Madurai.

4. Mr Senthil kumar, M.Sc, M. Phil.,

Statistician

Sacred Heart Nursing College.

5. Mrs Prof. Devakirubai M.Sc.,(N) P h.D

Medical Surgical Nursing Department.

Sacred Heart Nursing College.

Madurai.

6. Mrs Andal M Sc.,(N) Ph.D

Associate Professor

Medical Surgical Nursing Department.

Sacred Heart Nursing College.

Madurai.

7. Mrs. Manjula M Sc.,(N) PhD

Associate Professor

Medical Surgical Nursing Department.

Sacred Heart Nursing College.

Madurai.

APPENDIX-III

TOOL TO ASSESS DEMOGRAPHIC VARIABLES AND CLINICAL PROFILE OF SAMPLES

PART-1

Demographic variables

1. Sex _____

2. Age _____

3. Education _____

4. Locality: urban / rural

5. Occupation: _____

6. Nature of diet at present: liquid/semisolid/solid diet

7. Do you have the habit of smoking?

Yes / no

a) if yes specify the duration.

b) No of cigarettes / beedi per day

8. Do you have the habit of tobacco or betel nut chewing?

a) Yes / no

a) If yes specify the duration

9. Site of the tumour _____

10. Tumour classification _____

11. How long you are taking the treatment for cancer?

a)Surgery_____

b)Chemotherapy _____

c) Radiation therapy _____

12. Dose and no of fractional dose of radiation therapy _____

13. Radiation therapy field _____

PART II

GRONINGEN RADIATION –INDUCED XEROSTOMIA QUESTIONNAIRE

. SL NO	QUESTIONS	PRE TEST				POST TEST 5TH DAY				POST TEST 10TH DAY			
		Not at all	A little bit	Quite a bit	Very much	Not at all	A little bit	Quite a bit	Very much	Not at all	A little bit	Quite a bit	Very much
		1	2	3	4	1	2	3	4	1	2	3	4
1.	Do you have a dry mouth during the day?												
2.	Do you have a dry mouth while going out												
3.	Do you have difficulties with eating due to dry mouth ?												
4.	Do you have a dry mouth during activities ?												

. SL NO	QUESTIONS	PRE TEST				POST TEST 5TH DAY				POST TEST 10TH DAY			
		Not at all	A little bit	Quite a bit	Very much	Not at all	A little bit	Quite a bit	Very much	Not at all	A little bit	Quite a bit	Very much
		1	2	3	4	1	2	3	4	1	2	3	4
5.	Do you have difficulties with talking due to a dry mouth?												
6.	Did you drink more during the day due to a dry mouth?												
7.	Do you have a dry mouth during the night?												
8.	Have you had difficulties with sleeping due to a dry mouth ?												

. SL NO	QUESTIONS	PRE TEST				POST TEST 5TH DAY				POST TEST 10TH DAY			
		Not at all	A little bit	Quite a bit	Very much	Not at all	A little bit	Quite a bit	Very much	Not at all	A little bit	Quite a bit	Very much
		1	2	3	4	1	2	3	4	1	2	3	4
9.	Do you need to drink during the night due to a dry mouth?												
10.	Have you had sticky saliva during the day?												
11.	Have you had difficulties with eating due to sticky saliva?												
12.	Do you have difficulties with talking due to sticky saliva?												

SL NO	QUESTIONS	PRE TEST				POST TEST 5TH DAY				POST TEST 10TH DAY			
		Not at all	A little bit	Quite a bit	Very much	Not at all	A little bit	Quite a bit	Very much	Not at all	A little bit	Quite a bit	Very much
		1	2	3	4	1	2	3	4	1	2	3	4
13.	Have you had sticky saliva during the night?												
14.	Did you have difficulties with sleeping due to sticky saliva ?												

SCORING

1-14 (1% - 25% → normal

15-28(26%-50%) → mild

29-42(51%-75%) → moderate

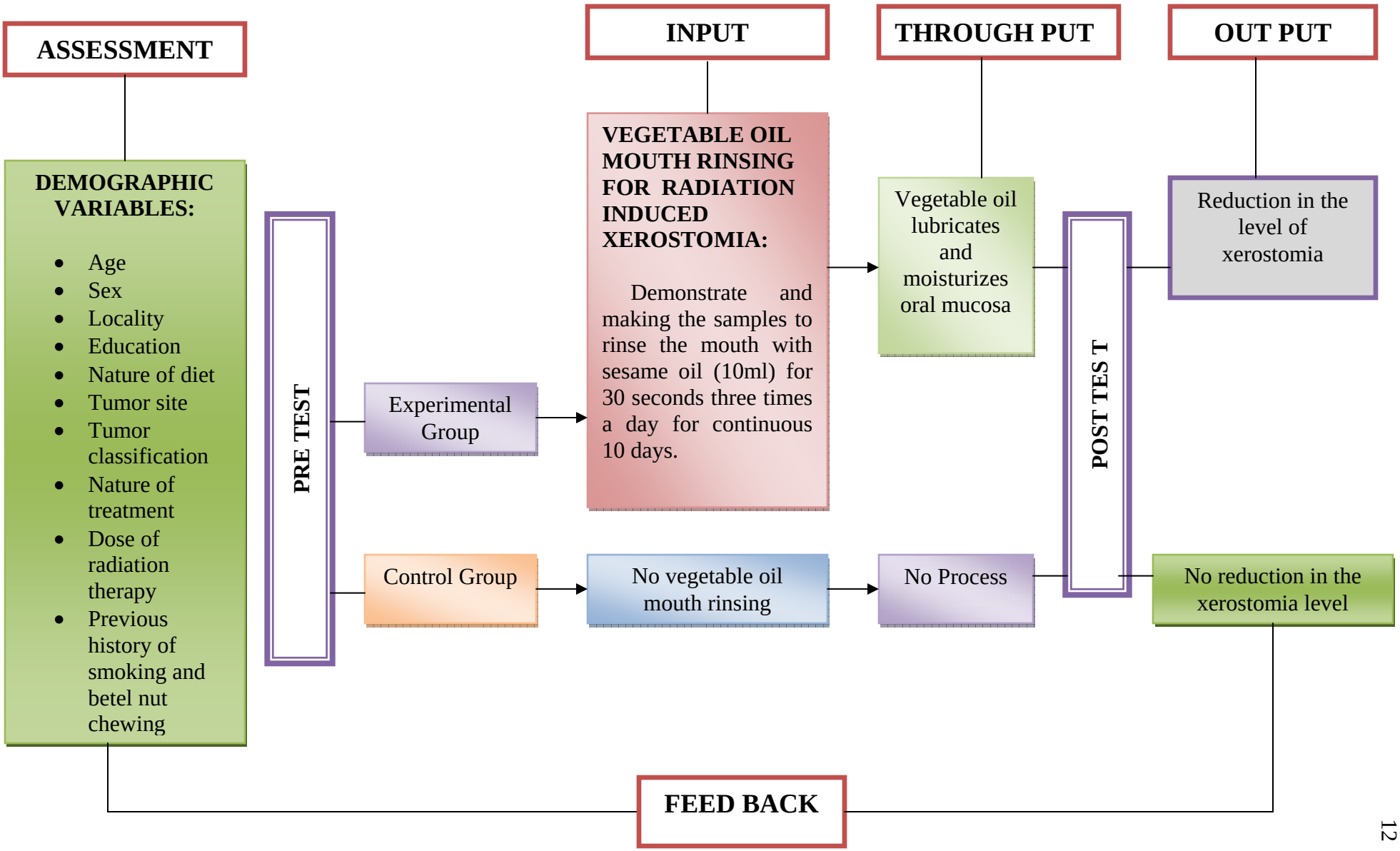
43-56(76%-100%) → severe

APPENDIX-IV

INTERVENTION STRATEGIES FOR XEROSTOMIA

- Subjects were instructed to take regular mouth wash, after that before taking the meals the samples were received the intervention by the investigator.
- One sachet containing 10 ml sesame oil was given to the subjects. Samples were asked to do the rinsing for 30 seconds producing bubbles in the mouth and asked to spit it out after rinsing.
- It was asked to be repeated three times a day before food for 10 continuous days and on 5^{th} and 10^{th} day samples were assessed for the post test score of xerostomia.

Figure:1 **CONCEPTUAL FRAMEWORK BASED ON JW KENNY'S OPEN SYSTEM MODEL**



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   Associate Professor
   Medical Surgical Nursing Department.
   Sacred Heart Nursing College.
   Madurai.

7. **Mrs. Manjula M Sc.,(N) PhD**
   Associate Professor
   Medical Surgical Nursing Department.
   Sacred Heart Nursing College.
   Madurai.

CERTIFICATION OF VALIDATION

This is to certify that the tool developed by Ms Thankam Thomas final year M.SC(N) student of Sacred Heart Nursing College ,Thasildar Nagar Madurai (affiliated to Dr.M.G.R.Medical university) is validated and can proceed with this tool and conduct the main study for dissertations entitled, "A **study to assess the effectiveness of vegetable oil in reduction of radiation induced xerostomia among patients receiving radiation therapy at a selected hospital in Madurai"**

Date: 25/6/11

Signature

Dr. G. AMARNATH, DMRT.,MBA.,
Senior Consultant Clinical and
Radiation Oncologist
Reg. No: KMC 23626
Apollo Speciality Hospital, Madurai-625 020

CERTIFICATION OF VALIDATION

This is to certify that the tool developed by Ms Thankam Thomas final year M.SC(N) student of Sacred Heart Nursing College ,Thasildar Nagar Madurai (affiliated to Dr.M.G.R.Medical university) is validated and can proceed with this tool and conduct the main study for dissertations entitled, **"A study to assess the effectiveness of vegetable oil in reduction of radiation induced xerostomia among patients receiving radiation therapy at a selected hospital in Madurai"**

Date: 23/6/11

Signature

(Dr. K. S Krishna Kumar)

CERTIFICATION OF VALIDATION

This is to certify that the tool developed by Ms Thankam Thomas final year M.SC(N) student of Sacred Heart Nursing College ,Thasildar Nagar Madurai (affiliated to Dr.M.G.R.Medical university) is validated and can proceed with this tool and conduct the main study for dissertations entitled, **"A study to assess the effectiveness of vegetable oil in reduction of radiation induced xerostomia among patients receiving radiation therapy at a selected hospital in Madurai"**

Date: 20/6/11

Signature

(Dr Nalini Jayavanth Santha)

CERTIFICATION OF VALIDATION

This is to certify that the tool developed by Ms Thankam Thomas final year M.SC(N) student of Sacred Heart Nursing College ,Thasildar Nagar Madurai (affiliated to Dr.M.G.R.Medical university) is validated and can proceed with this tool and conduct the main study for dissertations entitled, **"A study to assess the effectiveness of vegetable oil in reduction of radiation induced xerostomia among patients receiving radiation therapy at a selected hospital in Madurai"**

Date: 14/6/11

Signature

(Mrs Prof Devakirubai)

CERTIFICATION OF VALIDATION

This is to certify that the tool developed by Ms Thankam Thomas final year M.SC(N) student of Sacred Heart Nursing College ,Thasildar Nagar Madurai (affiliated to Dr.M.G.R.Medical university) is validated and can proceed with this tool and conduct the main study for dissertations entitled, **"A study to assess the effectiveness of vegetable oil in reduction of radiation induced xerostomia among patients receiving radiation therapy at a selected hospital in Madurai"**

Date:

Signature

(Mr Senthil Kumar)

APPENDIX-III

TOOL TO ASSESS DEMOGRAPHIC VARIABLES AND

CLINICAL PROFILE OF SAMPLES

PART-1

Demographic variables

1. Sex _____

2. Age _____

3. Education _____

4. Locality: urban / rural

5. Occupation: _____

6. Nature of diet at present: liquid/semisolid/solid diet

7. Do you have the habit of smoking?
   Yes / no
   a) if yes specify the duration.
b) No of cigarettes / beedi per day

8. Do you have the habit of tobacco or betel nut chewing?
   a) Yes / no
   a) If yes specify the duration

9. Site of the tumour _____

10. Tumour classification _____

11. How long you are taking the treatment for cancer?
a)Surgery _____
b)Chemotherapy _____
   c) Radiation therapy _____

12. Dose and no of fractional dose of radiation therapy _____

13. Radiation therapy field _____

PART II

GRONINGEN RADIATION –INDUCED XEROSTOMIA QUESTIONNAIRE

SL NO	QUESTIONS	PRE TEST				POST TEST 5TH DAY				POST TEST 10TH DAY			
		Not at all	A little bit	Quite a bit	Very much	Not at all	A little bit	Quite a bit	Very much	Not at all	A little bit	Quite a bit	Very much
		1	2	3	4	1	2	3	4	1	2	3	4
1.	Do you have a dry mouth during the day?												
2.	Do you have a dry mouth while going out												
3.	Do you have difficulties with eating due to dry mouth ?												
4.	Do you have a dry mouth during activities ?												

SL NO	QUESTIONS	PRE TEST				POST TEST 5TH DAY				POST TEST 10TH DAY			
		Not at all	**A little bit**	**Quite a bit**	**Very much**	**Not at all**	**A little bit**	**Quite a bit**	**Very much**	**Not at all**	**A little bit**	**Quite a bit**	**Very much**
		1	2	3	4	1	2	3	4	1	2	3	4
5.	Do you have difficulties with talking due to a dry mouth?												
6.	Did you drink more during the day due to a dry mouth?												
7.	Do you have a dry mouth during the night?												
8.	Have you had difficulties with sleeping due to a dry mouth ?												

SL NO	QUESTIONS	PRE TEST				POST TEST 5TH DAY				POST TEST 10TH DAY			
		Not at all	**A little bit**	**Quite a bit**	**Very much**	**Not at all**	**A little bit**	**Quite a bit**	**Very much**	**Not at all**	**A little bit**	**Quite a bit**	**Very much**
		1	2	3	4	1	2	3	4	1	2	3	4
9.	Do you need to drink during the night due to a dry mouth?												
10.	Have you had sticky saliva during the day?												
11.	Have you had difficulties with eating due to sticky saliva?												
12.	Do you have difficulties with talking due to sticky saliva?												

SL NO	QUESTIONS	PRE TEST				POST TEST 5TH DAY				POST TEST 10TH DAY			
		Not at all	A little bit	Quite a bit	Very much	Not at all	A little bit	Quite a bit	Very much	Not at all	A little bit	Quite a bit	Very much
		1	2	3	4	1	2	3	4	1	2	3	4
13.	Have you had sticky saliva during the night?												
14.	Did you have difficulties with sleeping due to sticky saliva ?												

SCORING

1-14 (1% - 25% ⟶ normal

15-28(26%-50%) ⟶ mild

29-42(51%-75%) ⟶ moderate

43-56(76%-100%) ⟶ severe

APPENDIX-IV

INTERVENTION STRATEGIES FOR XEROSTOMIA

- Subjects were instructed to take regular mouth wash, after that before taking the meals the samples were received the intervention by the investigator.

- One sachet containing 10 ml sesame oil was given to the subjects. Samples were asked to do the rinsing for 30 seconds producing bubbles in the mouth and asked to spit it out after rinsing.

- It was asked to be repeated three times a day before food for 10 continuous days and on 5^{th} and 10^{th} day samples were assessed for the post test score of xerostomia.